AD______________

Award Number: W81XWH-04-2-0006

TITLE: Conceptual Study of LSTAT Integration and Robotics

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REPORT DATE: August 2004

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	August 2004	Final (1 Jan 2004 - 31 Jul 2004)

4. TITLE AND SUBTITLE
Conceptual Study of LSTAT Integration and Robotics

5. FUNDING NUMBERS
W81XWH-04-2-0006

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

Original contains color plates: ALL DTIC reproductions will be in black and white

12a. DISTRIBUTION / AVAILABILITY STATEMENT	12b. DISTRIBUTION CODE
Approved for Public Release; Distribution Unlimited	

13. ABSTRACT (Maximum 200 Words)

Battlefield medicine is moving toward adoption of several new technologies to both improve the quality of care and protect healthcare providers. This has already begun through use of the Life Support for Trauma and Transport (LSTAT) patient transport litter. This study explores broader opportunities to integrate with LSTAT medical imaging, medical robots and other advanced diagnostic and therapeutic technologies to yield additional capabilities. New functionalities, potential timeframes for integration, and interoperability concerns are examined. Recommendations for a suite of technologies that can add value in the near term and create opportunities for future synergy are made.

14. SUBJECT TERMS	15. NUMBER OF PAGES
Robotics, Registration, LSTAT, Sensors, Diagnostic, Imaging, therapeutic	47
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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Acronyms

AED	Automatic External Defibrillator
ACV	Assist Control Ventilation
ARNG	Alaska Army National Guard
BAS	Battalion Aid Station
BAT	Blunt abdominal trauma
BIDS	Ballistic Impact Detection Sensors
BISD	Ballistic Impact Detection
CDDS	Clinical Decision-Support System
CPAP	Continuous Positive Airway Pressure
CRT	Cathode Ray Tube
CSH	Combat Support Hospital
CT	Computerized Tomography
DDLS	Display and Data Logging Subsystem
DICOM	Digital Imaging and Communications in Medicine
DOF	Degree of Freedom
ECG	Electrocardiogram
ECS	Environmental Control System
EIC	Electronic Information Carrier
EM	Electromagnetic
EPS	Electrical Power System
GUI	Graphical User Interface
GPS	Global Positioning Systems
HIFU	High Intensity Focused Ultrasound
HMMWV	High-Mobility Multipurpose Wheeled Vehicle
HUU	Handheld Ultrasound Unit
IR	Infrared
IV	Intravenous
LSD	Life Sign Detection
LSTAT	Life Support for Trauma and Transport
MULE	Multifunction Utility/Logistics and Equipment
MRI	Magnetic Resonance Imaging
MUSTPAC	Medical Ultrasound, Three-dimensional- Portable with Advanced Communication
NG-LSTAT	Next Generation - LSTAT
PEEP	Positive End Expiratory Pressure
PIC	Personal Information Carrier
SIMV	Synchronized Intermittent Mandatory Ventilation
SOF	Special Operation Forces
SOFMH	Special Operations Forces Medical Handbook
SOMDS	Special Operation Forces Medical Decision Support
US	Ultrasound
WEIC	Wireless Electronic Information Carrier.
WI-FI	Wireless Fidelity
WPSM	Warfighter Physiological Status Monitor

Introduction

Battlefield medicine is moving toward adoption of several new technologies to both improve the quality of care and protect healthcare providers. One example of this trend is use of the Life Support for Trauma and Transport (LSTAT) patient transport litter in combat conditions. LSTATs are sustaining lives on land, in the air and at sea from Alaska to Iraq. LSTAT was recently introduced into the nation's largest trauma center, Los Angeles County Trauma Center, where initial indications are that LSTAT not only helps save lives, but also helps save money. LSTAT has been deployed to 28th and 31st CSH in Iraq and Afghanistan and with a Navy amphibious assault ship. This includes LSTAT systems currently deployed with National Guard units in Alaska and Hawaii. LSTAT systems have recently been deployed with Special Operations teams in The Philippines, Cambodia and elsewhere. Military medical teams are being trained on the use of the LSTAT system at the Navy Trauma Training Center at Los Angeles County as well as University of Southern California (USC) Trauma Center. The 207th Alaska Army National Guard (ARNG) reports aeromedical rescue using the LSTAT system. The Alaska ARNG was tasked by 11th US Air Force to medevac a 70-year old male in Toksook bay with respiratory failure. The civilian air ambulance was not capable of flying due to high winds in Toksook Bay. The ARNG in Bethel was tasked and transported the patient in stable condition using the LSTAT. The patient was transported from Toksook bay to Bethel and his life was saved. Johnson and Pearce conducted a study where thirty-one anesthesiologists and recovery room nurses compared the LSTAT with conventional monitors while managing four simulated critical events. The preliminary evaluation of LSTAT in simulated and postoperative environments demonstrated that the LSTAT provided appropriate equipment to detect and manage critical events in patient care [1].

By virtue of its integrated patient monitoring and life support capabilities, LSTAT represents state-of-practice in battlefield medicine allowing patients to be cared for with less direct attention by medics during transport to Battalion Aid Station (BAS) and Combat Support Hospital (CSH) facilities. Objective Force Warrior (OFW) and Future Combat System (FCS) doctrine provides for small units of action (UA's), capable of rapid movement over wide areas of terrain, with embedded medics and medical teamsCSH, if they continue to exist, will be not be part of a UA but will be farther back as part of Unit of Employment (UE) support for UA's. As such, capabilities provided by LSTAT and related combat casualty care systems will become increasingly important to fighting forces of the future.

This report examines opportunities to further advance LSTAT to a next generation through the addition of and interfaces to advanced medical technologies, including robotics, information systems, sensors and other medical devices, that are either currently under development or contemplated for the near future, i.e., within 10 years. It explores broad concepts to combine the LSTAT and robotic systems to yield diagnostic, life support and therapeutic capabilities that neither LSTAT nor robotics could provide alone. We hypothesize the addition of several technologies to LSTAT and for each examine the data communication interfaces, computational requirements, power and volume utilization, and needs for modifying the current LSTAT architecture to accommodate new technologies. In addition, we speculate on value added by each technology, as well as the time frame within which it will be mature enough for field deployment. Based on all of these considerations, we conclude by selecting the top five technology candidates. Through incorporation of these technologies into the "Next Generation LSTAT (NG-LSTAT)", both the spectrum and level of care that can be provided to wounded warfighters can be dramatically increased.

1.Technology Market Research

In order to develop parameters for the Next Generation LSTAT (NG-LSTAT) system design, we first developed a requirements and workflow analysis for the earliest stages of combat casualty care, then summarized the capabilities of the current LSTAT system, as described below

1.1 Combat Casualty Care Requirements Analysis

Nearly 50 percent of combat deaths have been due to hemorrhage. Of those, it is speculated that about half could be saved if timely, appropriate care had been available. Head injuries and lung injuries are also major causes of death where proper treatments and training could significantly reduce mortality and morbidity. The treatment of battlefield casualties is exacerbated by the long evacuation times often found in military operations. This requires battlefield medics and physician's assistants to stabilize patients for extended periods and makes battlefield trauma care markedly different from civilian trauma care. Because approximately 86 percent of all battlefield deaths occur within the first 30 minutes after wounding, the ability to rapidly locate, diagnose, and render appropriate initial treatments are vital to reversing the historical outcomes of battlefield injuries. There are also new trends to cope with: recent experience from Operation Iraqi Freedom and Operation Enduring Fredeom shows unprecedented percentages of casualties are wounds to the extremities, head wounds and behind-body-arnor injuries. The need to provide the best possible care with a reduced logistics footprint is the cornerstone around which the future of combat casualty care research is built.

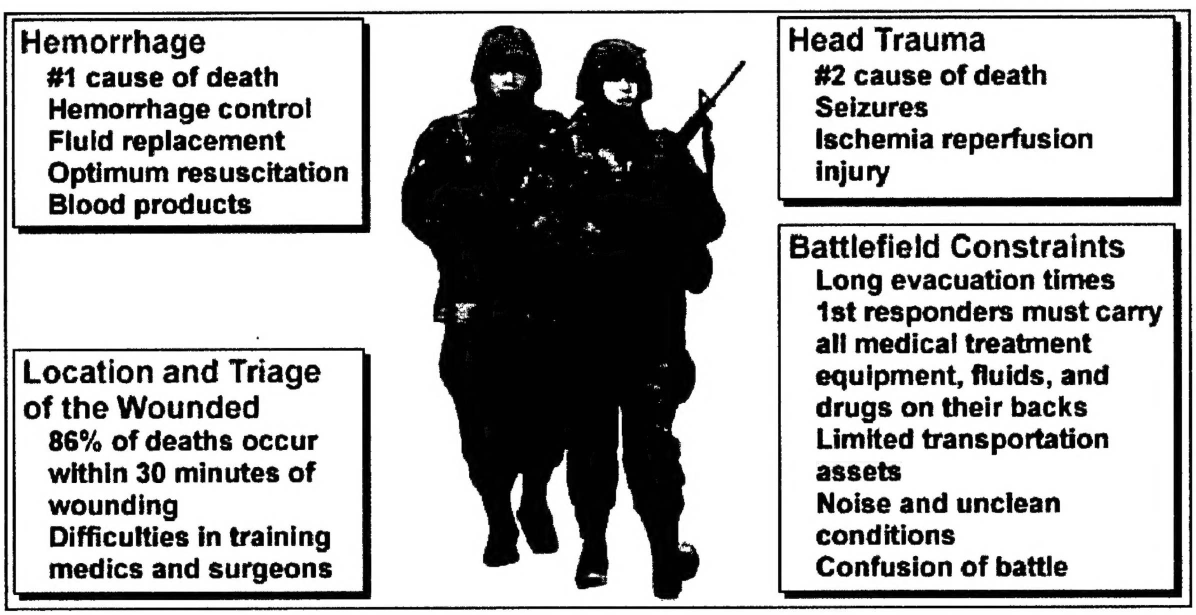

Figure 1 Combat Injuries

1.1.1 General Current Practices

When warfighters are wounded and still exposed to enemy fires, the number one priority for first-responders is to stabilize, then rapidly evacuate casualties by ground/air. On a battlefield, medics practice triage to divide casualties into three general groups:

- Group I: those killed outright or severely wounded past any help.

- Group 2: severely wounded requiring continuous medical support and supervision. This group can be divided into groups 2a and 2b in order to change providing care in the battlefield from golden hour to the golden minute.
- Group 3: those requiring minimal attention until they undergo definitive surgery.

A first responder will generally conduct the following procedures in order:

(1) Airway management:
- Chin lift or jaw thrust
- Unconscious casualty without airway obstruction: nasopharyngeal airway
- Unconscious casualty with airway obstruction: cricithyroidotomy

(2) Breathing: Consider tension pneumothorax and decompress with needle thoracostomy if a casualty has unilateral penetrating chest trauma and progressive respiratory distress

(3) Bleeding: Control any remaining bleeding with a tourniquet or direct pressure

(4) Intravenous fluids (IV's): Start an IV with an 18-gauge needle

(5) Fluid resuscitation:
- Controlled hemorrhage with shock: 1000 cc Ringer's Lactate
- Controlled hemorrhage without shock: no fluids necessary
- Uncontrolled (intra-abdominal or thoracic) hemorrhage: no IV fluid resuscitation.

(6) Inspect and dress wound.

(7) Check for additional wounds.

(8) Analgesia as necessary: Morphine 5 mg IV, wait 10 minutes; repeat as necessary.

(9) Antibiotics: As indicated by the battalion surgeon.

(10) Splint fractures and recheck pulse if not already done.

Also generally, first responders use the "ABCD" first aid method:

A) Make sure the victim's AIRWAY is open.

B) Monitor their BREATHING.

C) Check the victim's CIRULATION by monitoring their pulse rate, checking for severe bleeding, and checking the individual's skin color, temperature and moisture.

D) Check for DISABILITY. Medical personnel will need to know both the victim's mental and physical status.

1.1.2 Anticipated Advancements

To provide better combat casualty care and to better protect field medics, a number of new technologies are currently being deployed as prototypes, are under development or are being contemplated. Since their implementation may make use of LSTAT, it is important to understand how they and LSTAT will relate to each other in future scenarios. While a comprehensive review of those technologies is beyond the scope of this study, below we

describe their general applications and provide examples. The list is presented in approximate increasing degree of technological difficulty.

1. *Telementoring & teleconsultation – use of cameras and video telemetry for visual observation of wounded soldiers by medical experts in a remote location (though usually a short distance away) who verbally communicate back to the first responder.* Though many modern warfighters have helmet-mounted cameras and microphones, whose outputs can be transmitted to higher echelons, use of those devices has not been successful. In the future, telemedicine will likely be more comprehensive: the wounded soldier's physiological data and/or medical images will be included in addition to video and audio. For example, LSTAT's built-in sensing capabilities and wearable sensors being developed in the Warfighter Physiological Status Monitoring (WPSM) project might provide information on vital signs and ultrasound images acquired by man-portable units and/or digital x-rays acquired in field ambulances would be transmitted.
2. *Medical decision support – computerized retrieval of medical information in the field.* An example is the Battlefield Medical Information Systems – Tactical (BMIS-T), BMIS-T is a point-of-care hand-held assistant that enables military healthcare providers to record, store, retrieve and transmit the essential elements of clinical encounters on a palm-top computer. It also stores medical reference materials, such as the Special Operations Forces Medical Handbook. Such systems are currently based on wearable computers, palmtop computers or personal digital assistants (PDA's); in the future they will likely feature heads up displays and voice input.
3. *Unmanned evacuation – use of robots to transport patients from the battlefield to higher echelons of care.* As part of the military's overall Future Combat Systems effort, there are several projects currently underway to develop mobile robots capable of transporting wounded soldiers, under the assumption that they will be already stabilized on an LSTAT.
4. *Remote interventions – use of teleoperated robots for surgery at a distance (also known as "telepresent surgery").* Originally spearheaded by DARPA's Advanced Biomedical Techologies Program, there are now commercially available robots that perform laparoscopic procedures under the guidance of a surgeon. The most common example is the daVinci system, made by Intuitive Surgical, Sunnyvale, CA. In normal civilian use, the surgeon runs the robot from a console located in the operating room, though a few procedures have been done with doctor and patient separated by thousands of miles. An early design for the Future Combat Systems medical treatment vehicle includes a surgical camera and capabilities to support telepresent surgery.
5. *Unmanned extraction – use of robots to pull a wounded soldier from the line of fire.* Companion projects to unmanned evacuation robots are developing smaller robots that will move wounded soldiers over short distances. Some scenarios call for the robot to actually place the patient onto an LSTAT.
6. *Robotically assisted interventions – use of robots for guiding placement of medical instruments, including imaging sensors and interventional devices.* State of art in medical robotics is the use of robots to automatically locate a needle, drill or saw guide relative to a specific anatomical target based on directives from a physician who interactively locates the target in medical imagery. Such image-guided systems are available for biopsy, brachytherapy, and a variety of orthopaedic surgical procedures. Research prototypes have also been developed to position ultrasound transducers.

7. *Medical informatics – automated processing and analysis of patient data to assist the medic.* One of the earliest (and to this day, elusive) applications of artificial intelligence is computer-based interpretation of patient data for automatic diagnosis. An anticipated future capability is comparison of a wounded soldier's internal anatomy (based on data from field medical imagers) to his pre-wounded anatomy (e.g., as represented by a whole-body scan) stored digitally on the soldier's Personnel Information Carrier. While this can be done now for skeletal anatomy, techniques to compensate for deformation of soft tissue from one scan to the next do not yet exist. A basic requirement for futuristic autonomous medical informatics based assessment, diagnosis, and treatment is a complete "virtual human" model which includes complete physiological, anatomic, organ system, tissue, cell and genomics models of individual soldiers.
8. *Automated interventions – use of autonomous robots for interventions.* At present, such use of robots is only contemplated, though it is possible to make some general statements about the technologies. First, automated interventions will incorporate aspects of both image guided interventions and surgical robots. The robot's actions will be planned using real time 3D medical imaging, possibly augmented with pre-operative images of the patient (if available) and/or general anatomical atlases. Sophisticated automatic segmentation and analysis techniques will support interpretation of those images. The robot's coordinate frame will be registered to the patient using image-based and/or surgical navigation techniques. The latter involves the use of optical or electromagnetic markers that are attached to the patient and affixed to surgical instruments; surgical navigation is used now in a number of interventions, particularly orthopaedic surgery. Many future scenarios call for robots to remove clothing and body armor; adjust the position of casualty on the litter or LSTAT; move imaging and examination equipment into position; inject or apply analgesics, antibiotics, and anesthetics; and debride and close wounds.

A more comprehensive discussion of the use of robots in medicine and surgery is the Final Report on the International Advanced Robotics Program's Workshop on Medical Robotics [11].

1.2 Current LSTAT Capabilities, Interfaces and Usage

<u>1.2.1 System Overview</u>

LSTAT is a portable individual intensive care unit for resuscitation, stabilization and evacuation of trauma casualties. Figure 2 shows overall views of the LSTAT.

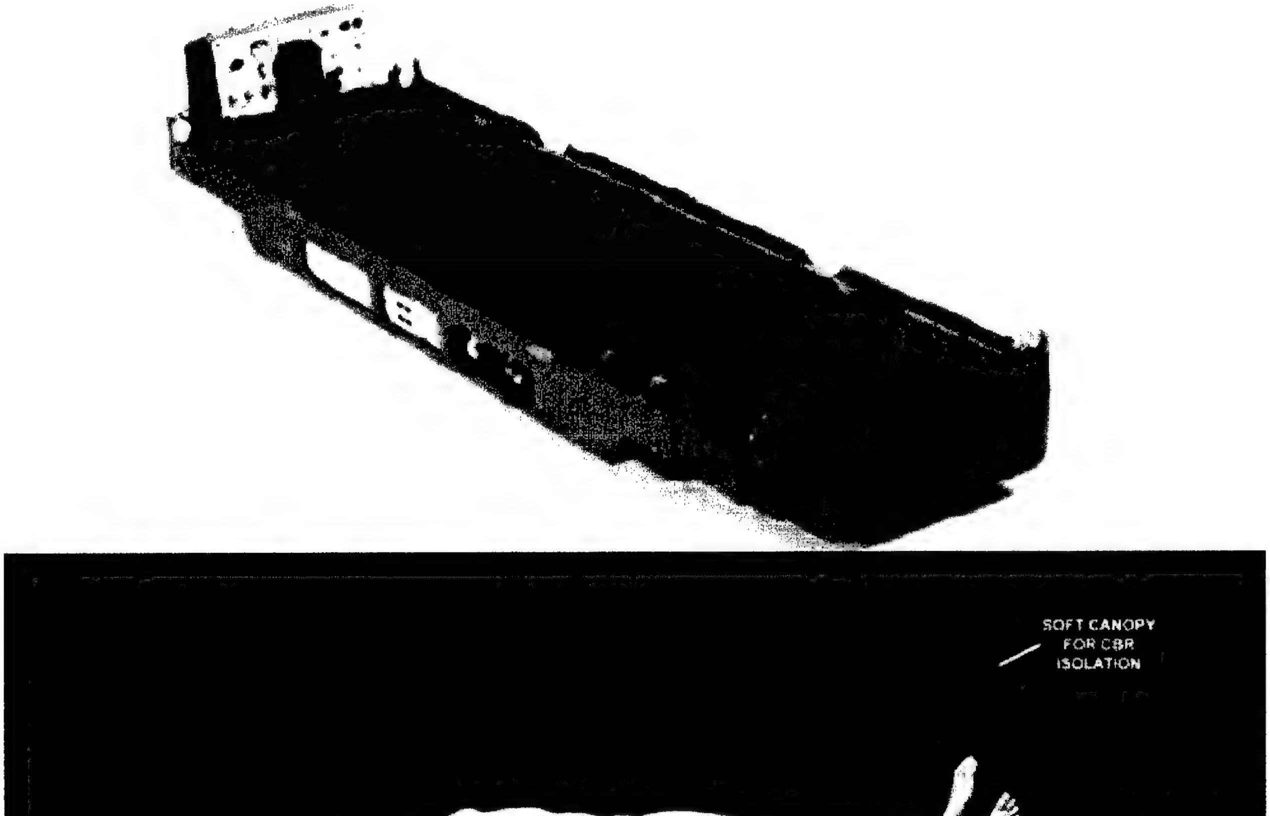

Figure 2 LSTAT

LSTAT physical, power and environmental characteristics are listed in the following tables.

Table 1-1: LSTAT Physical Characteristics

Weight	152 lbs base weight; 174 lbs with stretcher, oxygen bottle and regulator)
Dimensions	13" high, 86" long, 22" wide

Table 1-2: LSTAT Power Requirements

Electrical Power	115 ±10% VAC, 60±5Hz, single phase 113 ± 5%VAC 400±7Hz, single phase 230 ±10% VAC 50±3 Hz, single phase 25 ±5 VDC	In austere circumstances where portable generators are used, LSTAT requires at least 1 KW, 120 Volts AC to operate.
Batteries	Rechargeable Nickel-Cadmium (NiCad)	Greater than 30 minutes operation

Table 1-3: Environmental Conditions

Temperature Operating Storage	 +10 °C to +40 °C 0 °C to +40 °C
Relative Humidity Storage Operating (Planned)	 15% (6 hr.) 95% 29 °C (4 hr)

LSTAT is designed to operate in a "relatively controlled" environment. The system contains an environmental control system (ECS) for internal cooling, and can operate under the environmental conditions listed above.

1.2.2 Measurements and Treatments

LSTAT includes an onboard Physiological Monitoring Unit, Suction Unit, Defibrillation Unit, Fluid Administration Unit, Ventilator, Oxygen Subsystem, self contained Power Source and Electrical Power Subsystem, Internal Environmental Control Subsystem, Portable Clinical Analyzer, Display and Data Logging Subsystem and a secondary wireless Data Entry Workstation. Table 1-4 lists the LSTAT subsystems.

Table 1-4: LSTAT Measurements and Treatments

Subsystem	Measurement / Treatment
Physiological Monitoring	Electrocardiogram (ECG) Blood Pressure (Non-Invasive) Blood/Intracranial Pressure (Invasive) Temperature End tidal and inspired CO_2 Apnea Events Breath Rate Pulse Oximetry Ventilatory Pressure and Flow
Portable Clinical Analyzer	Blood chemistry analysis (Na, K, Cl, Glu, Lac, Crea, PH, PCO2, PO2
Suction	Continuous and Intermittent Modes
Defibrillator	Automated external defibrillator, preprogrammed, paste-on electrodes
Intravenous (IV) Fluid & Drug Infusion	Three independent flow pumps
Electrical Power System (EPS)	Self-contained Auxiliary Mode
Environmental Control	Provides clean filtered air at temperature below 40 °C with air velocities above 100 ft/min
Oxygen System	Internal: 840 l of Oxygen at 3000 PSI, Delivers 8 l per min. for 1 hr External: Both sides of LSTAT, Oxygen supply of 40-55 PSI

Subsystem	Measurement / Treatment
Ventilator	Mandatory Assist modes Ventilation Parameter Controller Onboard Medical Air Supply Onboard Air/O_2 Blender Gas inputs Ventilation parameters Physiological/Performance Numeric displays Physiological/Performance Waveform display Altitude Compensation Adjustable Pressure Thresholds Adjustable Alarm Sources Non-adjustable Alarm Sources
Display and Data Logging Subsystem (DDLS)	Operational Mode: Perform data logging functions Maintenance Mode: used for parameter setting and data logging
Secondary Data Display Workstation	Display secondary display of the LSTAT Subsystems

1.2.2.1: Display and Data Logging Subsystem (DDLS)

DDLS records physiological data for the patient and records status of LSTAT equipment. The DDLS logs data for up to 72 hours of continuous use. At startup, LSTAT performs an automatic built-in-test to determine the operational health of the DDLS. The DDLS has 2 modes, operational and maintenance. In operational mode, the DDLS performs data logging functions and provides interactive displays and controls for an operator to view data or download logged data to an off-board computer. Maintenance mode is used for parameter setting and data logging.

1.2.2.2: Secondary Display Subsystem

A Pentium-based tablet PC, currently running Windows 98 operating system, which would display data, graphs and EKG wave forms from various LSTAT subsystems. Figure 1-3 shows both the DDLS and the Secondary Display Subsystems.

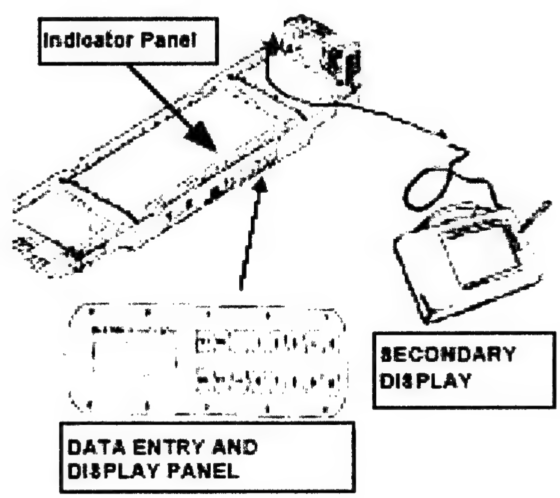

Figure 3 DDLS and Secondary Display Subsystem

1.2.2.3: Physiological Monitoring

The LSTAT has the capability to monitor the patient status and functions continually and to report those anomalies that occur with the patient to the operator. Monitoring functions include: Non-Invasive Blood Pressure, two channels of Invasive Blood Pressure, Electrocardiogram (ECG), Pulse Oximetry (SpO2), Airway Carbon Dioxide (CO2), Airway flow and Volume, and

Temperature (esophageal or skin). Each of the measured parameters is range checked and the alarm condition posted as necessary. The monitored information is delivered to the Display and Data Logging Subsystem (DDLS).

1.2.2.4: Portable Clinical Analyzer

Blood chemistry or cerebral fluid chemistry analysis is accomplished with a handheld, portable unit and has the capability to perform various blood testing. Blood cerebral fluid testing is accomplished by the use of disposable cartridges that are inserted with the sample into the instrument for analysis. The Portable Clinical Analyzer can perform blood tests for sodium, potassium, chloride, glucose, urea nitrogen, hematocrit, ionized calcium, arterial blood gases, (pH, PCO2, and PO2), and bicarbonate. In addition, certain other values, such as carbon dioxide, base excess, anion gap, hemoglobin and O2 saturation, can be derived by calculation from the tests performed. The Portable Clinical Analyzer operates on two (2) 9-Volt lithium batteries can store up to 50 patient records and can transmit individual or groups of records via infrared signals (IR) to the DDLS. Data can also be viewed on the analyzer screen itself.

1.2.2.5: Suction Unit

The Suction Unit is designed for removing secretions from the upper airway during otopharyngeal, nasopharyngeal and tracheal suctioning procedures; programmable gastrointestinal and abdominal wound drainage; or surgical site debris removal in field hospitals.

1.2.2.6: Defibrillator

The semi-automatic defibrillator monitors and analyzes a patient's Electrocardiogram (ECG) to apply defibrillation shocks, when required. The ECG analysis circuitry assesses the electrode conditions and signal waveform. When lethal arrhythmias are detected, the defibrillation circuitry is automatically charged and an advisory is issued that the defibrillation pulse should be applied. If the operator authorizes the discharge, then the discharge is applied through the patient electrodes. If the operator fails to authorize the shock application to the patient within 30 seconds, then the charge is dumped into an internal dummy load. Patient ECG and response to counter shock are recorded.

1.2.2.7: Fluid & Drug Infusion

The infusion pump can be used for epidural administration of anesthetic and analgesic drugs. The multichannel infusion pump delivers resuscitation levels of intravenous solutions and multiple drugs at rates from .1 to 999 cc/hour on each of its three channels. The pump has its own 6-hour nickel cadmium battery to function in the absence of LSTAT power. The unit reports fluid types, rates and related information to the Display and Data Logging Subsystem, however using the infusion pump on its own battery power without LSTAT power will not allow data to be captured by the DDLS. For specific drugs, the instrument calculates a volumetric or dose rate based on values entered for patient's weight, drug concentration and dosing parameters as follows.

1) Program the patient's weight in Kg
2) Choose the desired concentration
3) Program a dose.
4) The volumetric rate is automatically calculated.

1.2.2.8: Ventilator

The ventilator system contains an electronically controlled ventilator, compressor, and air/oxygen mixer to supply the patient with medical grade air and oxygen. It is controlled by an internal microprocessor that continuously monitors and displays airway pressure, control settings, alarm parameters, gas source, gas flows, gas blends and power signals. An adjustable pressure limit control limits peak inspiratory pressures and high-pressure alarm set point. Automatic ventilator backup assures continued mechanical support if the patient becomes apneic. A Manual Breath button permits manual delivery of ventilation at any time. The ventilator is designed to operate from the LSTAT power supply; ventilator data is presented on the Secondary Display data.

1.2.2.9: Oxygen System

The oxygen system provides oxygen to a gas blender to mix with ambient air for the ventilator. An internal oxygen bottle has the capacity to hold 480-liters of oxygen at 3000 psi and deliver 8 liters per minute for 1 hour. Ports located on both sides of LSTAT (Figure 1-2) permit connection of an external oxygen supply of 40-55 psi. When external oxygen is used, flow from the internal oxygen bottle stops. A ventilator bypass oxygen port is available on the LSTAT head fairing for connecting a cannula or a mask. There is no oxygen flow regulation at the bypass port, so flow regulation is accomplished using a flow regulator attached to an external tube on the oxygen mask.

1.2.2.10: Electrical Power System (EPS)

The LSTAT EPS interfaces with auxiliary power from multiple evacuation and air/ground-based environments utilizing five separate adapters. It also has the capability to be re-charged/re-energized and can operate autonomously for at least 30 minutes. High performance Nickel-cadmium batteries are used and can be recharged in place and/or exchanged.

The EPS provides a smooth uninterrupted transition between self-powered and auxiliary modes. See Figure 2-5 for external electrical connections. Controls are provided for managing any power source and support the automatically controlled recharging of self-contained power stores during periods of AC auxiliary power connection. Recharging can be completed within a 24-hour time span for a completely discharged system.

1.2.2.11: Environmental Control

The Environmental Control System (ECS) provides LSTAT equipment with clean filtered air at temperatures below +40 0C with air velocities above 100 ft/min, when ambient temperatures are above +25 0C, with no condensed moisture. Air is brought in through inlets located on either side of the head fairing and is exhausted through vents located adjacent to the foot compartment. System over temperature conditions are indicated on the side mounted ECS indicator panels and transmitted to the DDLS as well. Various distributed critical and typical sled locations are monitored with temperature sensors and recorded by the DDLS as well.

1.3 Medical Evacuation and Treatment Vehicles

1.3.1 Armored Medical Evacuation Vehicle

In the present inventory, the Armored Medical Evacuation Vehicle (AMEV) operates in the forward area with armored and mechanized battalions providing combat medical support, protection for casualties, evacuees and combat medics. AMEV is designed for transporting up to 4 patients on LSTAT's. Figure 4 Armored Medical Evacuation Vehicle (AMEV) Right: exterior; Left: interior

shows an image of the AMEV 300.

Salient characteristics of the AMEV are:

- Weight (combat loaded): 50,000 LBS
- Electrical System:
  (2) generators, one providing 300A @ 28 VDC, one providing 400A @ 28 VDC:
  (4) type 6TN batteries, each providing 100A @ 12VDC
- (1) 1KW 115 VAC, 60Hz inverter:
- Life support: Basic Airway, Oxygen, Suction, Bleed Control, Vital Signs monitor, LSTAT for advanced airway, ventilation, fluid challenge and drugs.

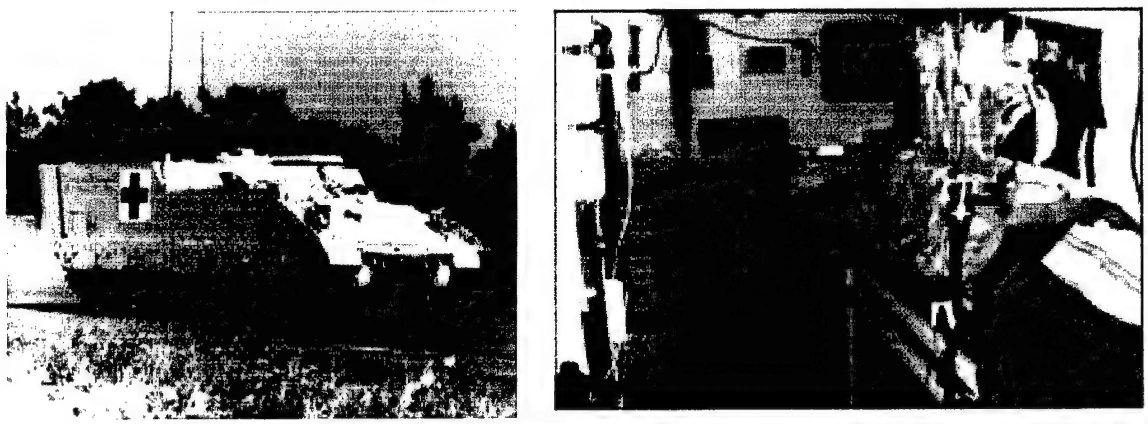

Figure 4 Armored Medical Evacuation Vehicle (AMEV) Right: exterior; Left: interior

1.3.2 Future Combat Systems

In the transition to Future Combat Systems (FCS), a new platform will be used. The FCS Medical Treatment Vehicle (MTV), being developed by United Defense LP, is a variant on the Future Combat Troop Carrier. It is a 16-ton class vehicle with a 3-person crew. It will include the capability to carry litter and ambulatory patients as well as essential medical items and equipment in a protected casualty treatment workspace. In contrast to current doctrine, FCS will provide a broader array of options for managing combat casualties, such medical imaging, telemedicine that reaches back to stateside facilities, and secondary and even tertiary interventions that are far forward.

Original Army Future Combat System (FCS)
Medical Treatment Vehicle (MTV)
Electronics Hardware Architecture

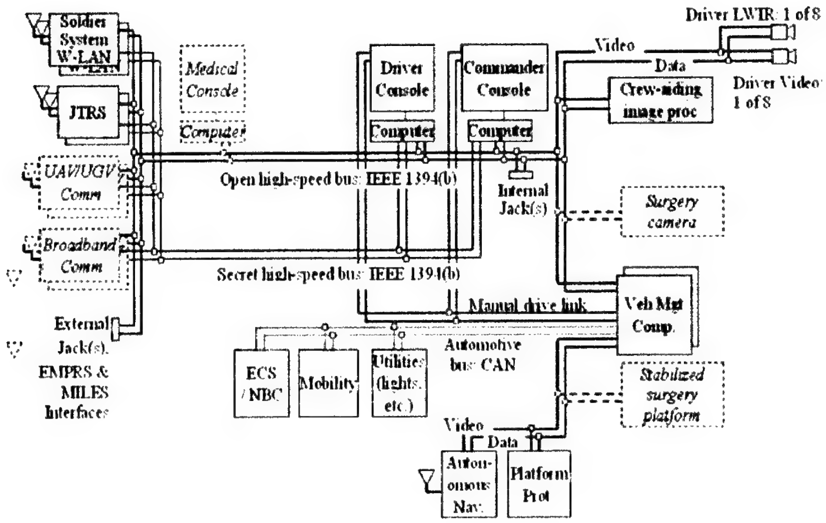

Figure 5 high level block diagram of Future Combat System Medical Vehicle

1.3.3 Robotic Extraction and Evacuation

Advanced concepts for combat casualty care feature mobile robots that will extract and evacuate wounded warfighters. Some are illustrated in the following figures.

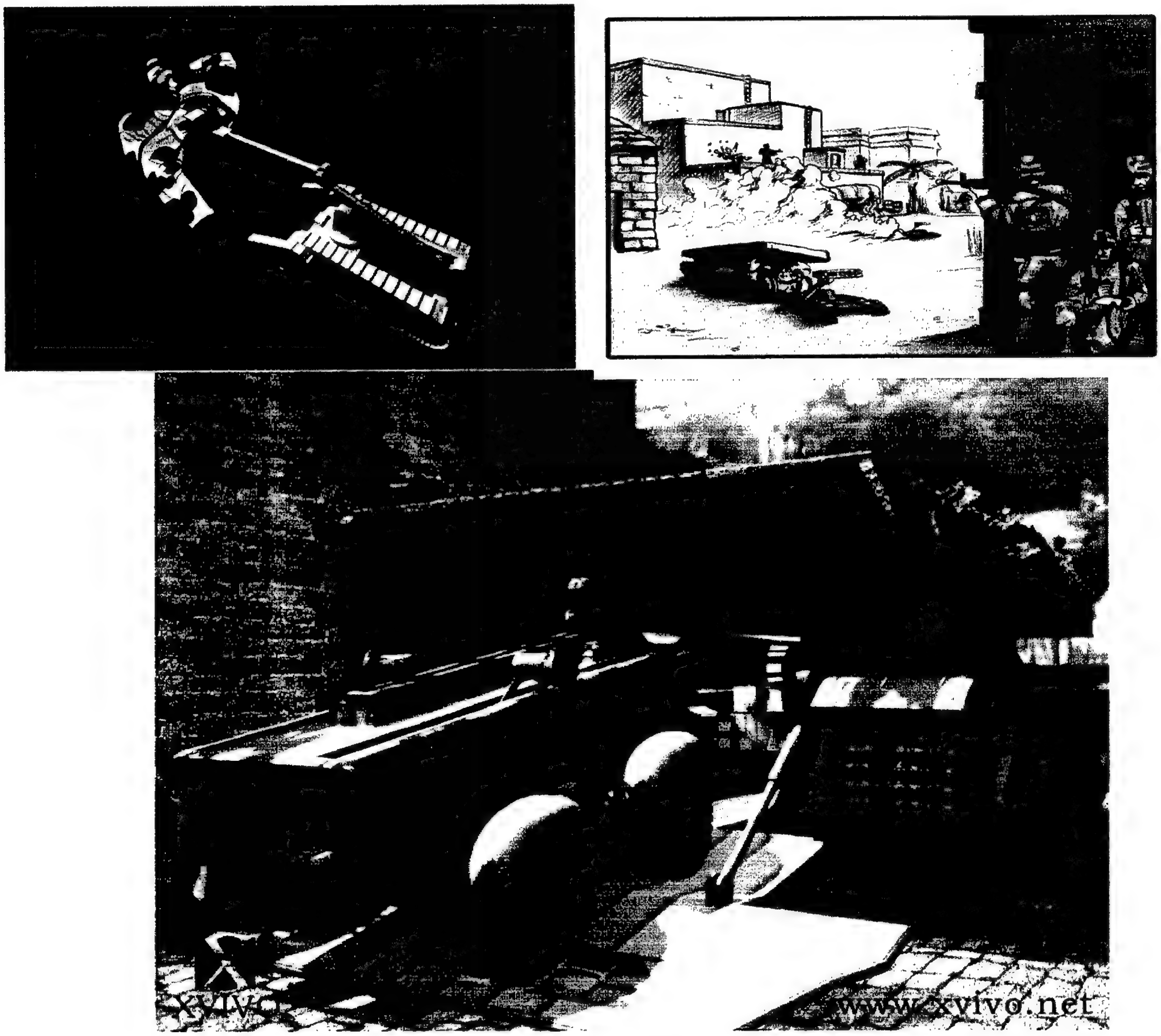

Figure 6 concepts for evacuation by robots and patient transfer to LSTAT

1.4 Current Uses of LSTAT in Field Conditions

The LSTAT is being used at the Combat Support Hospital (CSH) level in Iraq and Afghanistan and during a peacekeeping mission in Southeast Asia. It was brought forward to the Battalion Aid Station (BAS) during deployment to Kosovo. Currently LSTAT is being used for the following medical conditions:

1) Shock
2) Lack of consciousness
3) Internal/ External Hemorrhage
4) Head injury
5) Spinal injury

After the patient is placed on the LSTAT the health care provider (medic) enters the LSTAT ID, provider ID, the Patient ID into the Display and Data Logging Subsystem (DDLS) and start the physiological monitoring unit.

2. Conceptual Study Design

2.1 Overview and Methodology

Our hypothesis is the Next Generation LSTAT will be an improvement on LSTAT through incorporation of robotics and other diagnostics/therapeutics devices. We developed lists of candidate technologies that might be integrated with NG-LSTAT, either for stand-alone field operation or for use in conjunction with NG-LSTAT inside a vehicle or at an aid station. The technologies examined fall into the classifications

- medical imaging,
- other diagnostics,
- first aid,
- secondary and tertiary care,
- medical informatics, and
- telecommunications.

For each capability listed in the tables, we consider the following implications to its incorporation to NG-LSTAT.

1. Consumption is the amount of NG-LSTAT budgets (cube, power, weight, local intra-LSTAT communications bandwidth and CPU usage) consumed by the added technology. Intra-LSTAT communications refers to data exchange between NG-LSTAT and devices that are used locally to it when NG-LSTAT is in stand-alone mode, i.e., by itself in the field. This is in contrast to off-board communications which refers to data exchange between NG-LSTAT and devices that are part of larger infrastructure, e.g., an AMEV, BAS or CSH]. Consumption is quantitative and measurable.

> <u>Example</u>: Fibrin bandages
> Cube = .001 m3
> Power = 0 W
> Weight = 0.5 kg
> Intra-LSTAT bandwidth requirements = none
>
> <u>Example</u>: portable ultrasound unit
> Cube = 0.05 m3
> Power = 100 W
> Weight = 15 kg
> intra-LSTAT bandwidth requirements = 1 MB/sec (megabyte per second), assumes acquired images, each 256 x 256 pixels, 1 byte per pixel, 30 images per second, 50% compression) are transferred to NG-LSTAT's computer for display in real time.

2. Availability describes the maturity of the added technology both in terms of two factors: the timeframe within which it can be expected to be available for integration to NG-LSTAT and the R&D effort needed to maturate the technology. The latter captures the technological difficulty of realizing the capability, which is affects but does not necessarily drive the timeframe. For example, even though the technical R&D may be complete, it may be several years for a technology to be available if it has not yet been cleared by the FDA.

3. Interdependency is the extent to which an added technology and NG-LSTAT are coupled together or depend on each other to achieve the intended capability. It ranges from low, i.e.,

when the added technology is merely "along for the ride" to high, i.e., the when desired capability is only achievable through tight integration of the added technology and NG-LSTAT. Any needs to make significant design changes to the current LSTAT platform are factored in. Interdependency is semi-quantitative; we provide ratings on a scale of 1 (low) to high (5).

Example: medical image analysis software
Interdependency = 5
Explanation: requires NG-LSTAT computer
Example: portable ultrasound unit
Interdependency = 2
Explanation: (assuming that acquired images are displayed on the NG-LSTAT monitor as a matter of convenience and possible merging with other data and imaging modalities, but the ultrasound unit is otherwise self-sufficient for image acquisition)

Example: local area networking
Interdependency = 5
Explanation: communication between NG-LSTAT and diagnostic and therapeutic equipment is only necessary if they are used as a holistic system

4. *Benefits* are perceived worth of the technology under consideration. This includes the value it adds to the overall NG-LSTAT/medic system and the opportunities created for synergies with other Combat Casualty Care technologies. Benefits are subjective and scored on a scale of 1 (little worth) to 5 (great worth).

Example: pulse oximeter (wearable sensor to measure blood oxygenation)
Added value = 1
Opportunities for synergy = 1
Explanation: the functionality is already redundant with respect to LSTAT's built-in capabilities

Example: portable ultrasound unit
Added value = 4
Opportunities for synergy = 4
Explanation: provides on-site medical imaging capability and creates opportunities for image guided interventions using other equipment

Table 2-1 Diagnostics (Medical Imaging)

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value 1=little, 5=great	possible synergy	time frame	R&D required 1=none 5=much	
digital x-ray imaging	locate & measure internal bleeding; locate shrapnel; assess bone damage; assess soft tissue damage	large solid state receiver array ("digital plate")	several commercial versions (e.g., GE Healthcare Apollo)	When placed below patient, allows x-ray images to be taken without removing patient from litter.	0.02	20	5	10+	High	4	4	1-3 yrs	1	4
	move digital plate (in tandem with x-ray source)	linear servo positioning mechanism; could add limited additional pitch and roll articulation	concept	Enables 2D imaging of whole body; also makes 3D (open CT) imaging possible.	0.2 (total swept volume)	100 (est)	10 (est)	0.1	Low	5	5	1-3 yrs	2	5
ultrasound imaging	locate & measure internal bleeding; locate shrapnel; assess soft tissue damage	hand-held or laptop based diagnostic ultrasound unit	several commercial versions (e.g., Terason 2000, Medison Mysono201, SonoSite 180) of portable standalone units	Could be a) stowed but standalone, b) stowed and powered, c) built-in with direct data & power interfaces	0.1	50	3	10+	Med	4	4	0	1	2
	same as above but images are 3D volumes instead of 2D slices	a) 1D ultrasound element array with electromagnetic position tracking; b) 1D array with internal articulation; c) 2D array	MUSTPAC (Medical Ultrasound, Three-dimensional & Portable with Advanced Communications) prototype developed at Pacific Northwest National Laboratory	3D imaging generally more useful than 3D. Similar considerations for integration as for 2D ultrasound.	0.15	50	3	10+	Med	5	5	1-3 yrs	4	2
resistivity imaging	identify intracranial hematoma or pneumothorax	radio frequency triage system (RAFTS)	under development at Uniformed Services University of Health Sciences		0.01	5	2	1	Low	4	4	3-5 yrs	3	2

Table 2-2 Other Diagnostics

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value	possible synergy	time frame	R&D required 1=none 5=much	
										1=little, 5=great				
Wearable - vital signs	measure heart rate	digital ECG with skin surface electrodes	part of WPSM (Warfighter Physiological Status Monitor) sensor suite	WPSM hub links to NG-LSTAT computer	Note 1	Note 1	Note 1	0.01	Low	2 (Note 9)	1	now	1	2
	measure blood pressure	electronic cuff sensor			Note 1	Note 1	Note 1	0.01	Low	2 (Note 9)	1	now	1	2
	measure skin temperature	thermistor			Note 1	Note 1	Note 1	0.01	Low	1 (Note 9)	1	now	1	2
	measure respiration rate	strain guages; accelerometers			Note 1	Note 1	Note 1	0.01	Low	2 (Note 9)	1	now	1	1
	measure O2 saturation in blood	pulse oximeter	several commercial vendors; measures pulse rate		Note 1	Note 1	Note 1	0.01	Low	1 (Note 9)	1	now	1	2
Wearable - other measurements	report history of water intake	flowmeter built into canteen	part of WPSM sensor suite	recorded data added to patient's electronic medical record	Note 1	Note 1	Note 1	0.01	Low	2	1	now	1	2
	report history of sleep	motion monitors built in to wrist watch	part of WPSM sensor suite		Note 1	Note 1	Note 1	0.01	Low	1	1	now	1	2
	report history of ballistic impact	fiber optics	"Smart shirt" sold by Sensatex, Inc.		Note 1	Note 1	Note 1	0.01	Low	2 (Note 10)	3	now	1	2
Internal - vital signs	measure blood pressure and core body temperature	microelectromechanical systems (MEMS) devices built into catheters	several commercial vendors (e.g., Millar, Boston Scientific)	requires signal processing and data & power interfaces	neglig (Note 3)	Note 4	0.5	0.01	Low	3	3 (Note 2)	now	1	3
	measure blood pressure, flow & temperature	implantable MEMS sensors with wireless telemetry	pre-commercial prototypes (e.g., CardioMEMS) available	requires data receiver which needs data & power interfaces	Note 1	Note 1	Note 1	0.01	Low	1 (Note 9)	1	5-7 yrs (Note 6)	4	3
Internal - other measurements	measure concentration of body fluid analytes (Na/K ratio, lactate, pH)	implantable MEMS sensors & microdialysis with wireless telemetry	concept, e.g., Carnegie Mellon Shock Resuscitation Interstitial Microdialysis Probe	Measures indicators of shock; requires data receiver which needs data & power interfaces	neglig (Note 3)	Note 4	neglig	0.01	Low	5	2	3-5 yrs	3	2
	deploy internal sensors to locations not accessible with catheters	*in vivo* micro robots	e.g., Carnegie Mellon "HeartLander" prototype crawler for epicardial interventions	requires controller and data & power interfaces	0.1 (Note 7)	100 (Note 7)	5 (Note 7)	0.05	Med	3	3 (Note 2)	5-7 yrs	4	4

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value	possible synergy	time frame	R&D required 1=none 5=much	
										1=little, 5=great				
Visual inspection	observe patient from remote location	video camera on pan & tilt mount	several commercial vendors	requires data and power interfaces	0.05	50	2	100	Low	3	3	now	1	4
	examine patient from remote location	video camera on highly articulated robotic arm	commercial cameras; research prototype manipulators	requires data and power interfaces; high degree of articulation needed to inspect large area within small swept volume	0.1 (Note 7)	500 (Note 7)	5 (Note 7)	100	Med	5	5 (Note 8)	1-3 yrs	1	4

Notes

1. Worn by soldier, so no incremental consumption of NG-LSTAT resources
2. In vivo measurements are preferred in conjunction with hypothermia induction
3. Storage space required
4. Power drawn from on-board data acquisition system
5. Implantable sensors are essentially an alternative to wearable WPSM sensors
6. Pressure sensor currently in clinical trials; problem of biofouling for chronic use remains unsolved
7. Requirements are for robot controller & power supply
8. Creates opportunities for telemedicine and multiple additional capabilities
9. Redundant with respect to existing LSTAT capabilities
10. Useful in locating wounds quickly

Table 2-3 First Aid

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value (1=little, 5=great)	possible synergy (1=little, 5=great)	time frame	R&D required 1=none 5=much	
Hemostasis	seal wounds externally	fibrin bandage	2 versions currently in use	stowed as a supply	0.05 (Note 1)	-	1	-	-	5	1	now	1	1
	cauterize internal tissue	high intensity focused ultrasound (HIFU)	portable HIFU prototype (University of Washington)	could be a) stowed but standalone, b) stowed and powered, c) integrated with direct data & power interfaces	0.05	100	20	100 (Note 4)	High	5	4 (Note 2)	now (Note 3)	2	3
Airway management	assist endotracheal tube placement	ultrasound imaging	several commercial units available		0.1	50	3	10+	Med	4	4 (Note 5)	3-5 yrs	3 (Note 6)	3
		robot manipulator	concept only	requires power; could have standalone controller	0.1 (Note 7)	500 (Note 7)	5 (Note 7)	100	Med	4	3	5-7 yrs	5	3
Fluid replacement	assist peripheral venous catheter insertion	ultrasound imaging; artifical reality displays	e.g., University of Pittsburgh "Sonic Flashlight"	could be a) stowed but standalone, b) stowed and powered, c) integrated with direct data & power interfaces	0.1	50	3	10+	Med	4	5 (Note 5)	2-4 yrs	3 (Note 6)	3
		robot manipulator with needle guide end effector & force control	prototypes at Johns Hopkins University	used in conjunction with medical imaging	0.1 (Note 7)	500 (Note 7)	5 (Note 7)	100	Med	3	4 (Note 5)	5-7 yrs	5	3

Notes

1. Storage space required
2. Creates opportunities for telemedicine
3. FDA approval required
4. Is used in conjunction with ultrasound imaging
5. Multiple other uses
6. Basis technology exists but techniques to use it have yet to be developed
7. Requirements are for robot controller & power supply

Table 2-4 Secondary and Tertiary Care (see notes 1,3,8)

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value 1=little, 5=great	possible synergy	time frame	R&D required 1=none 5=much	
Wound treatment	debride wounds	imaging system and robot manipulator with forceps end effector	concept	could be teleoperated by remote medical personnel; requires medical and/or optical image analysis to be autonomous	0.1 (Note 7)	500 (Note 7)	5 (Note 7)	100	Med	4	4 (Note 5)	8+ yrs	7	3
	apply antibiotics	robot manipulator with sprayer end effector	concept		0.1 (Note 7)	500 (Note 7)	5 (Note 7)	100	Med	4	4 (Note 5)	3-5 yrs	7	3
Hyperthermia induction	assist central venous catheter insertion	robot manipulator with needle guide end effector	prototypes at Johns Hopkins University		0.1 (Note 7)	500 (Note 7)	5 (Note 7)	100	Med	4	4 (Note 5)	5-7 yrs	7	3
Tissue repair	surgical procedures such as clamping, suturing, shrapnel removal	surgical robot	e.g., daVinci laparoscopy robot (Intuitive Surgical, Inc.)		4	2000	250	100	High	4	4	8+ yrs	4	3
	deposit biologics in controlled patter (e.g., growth factors) for in vivo tissue engineering	robot manipulator with precision end effector	e.g., prototypes at Carnegie Mellon, Stanford, Univ. of Michigan		0.2	500 (Note 7)	5 (Note 7)	100	Med	3	3	2-4 yrs	5	3
Automation Support	track location of anatomical landmarks and medical/surgical instruments	surgical navigation system (fixed base station and targets affixed to medical instruments and to patient)	commercial optical and electromagnetic versions available	base station must be rigidly attached; power & data interfaces required	0.2	200	10	10	Med	3	4 (Note 5)	now	3 (Note 6)	2
	generate 3D surface profiles of patient	3D camera	laser rangefinder (several commercially available)	data facilitates robotic interventions	0.2	200	10	100	High	3	3	8+ yrs	3 (Note 6)	2

Notes

1. Storage space required
2. Creates opportunities for telemedicine
3. FDA approval required
4. Used in conjunction with ultrasound imaging
5. Multiple other uses
6. Basis technology exists but techniques to use it have yet to be developed
7. Requirements are for robot controller & power supply
8. Unlikely for secondary or tertiary care to be administered outside a Medical Vehicle or facility

Table 2-5 Medical Informatics

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value 1=little, 5=great	possible synergy	time frame	R&D required 1=none 5=much	
Decision support	support triage and diagnosis; provide step-thru instructions for various procedures	on-line medic's handbooks	Battlefield Medical Information Systems – Tactical (BMIS-T)	could be program on built-in computer or on standalone networked computer or PDA	Note 1	Note 1	Note 1	Note 1	Low	4	3	now	1	2
		speech capable personal digital assistant	prototype under development		neglig	10	0.5	10	Low	3	3	3-5 yrs	3	2
		wearble heads up display	retinal projection display; LCD goggles		0.01	30	1	10+	Low	3	4	now	2	2
Electronic medical records	retrieve patient medical history, known allergies, images, etc., carried by soldier	non-volatile flash memory	various commercial technologies available	referred to as electronic information carrier (EIC) or personal information carrier (PIC)	Note 3	Note 3	Note 3	10 (Note 4)	Low	4	4	now (Note 2)	2	2
Data logging	capture data collected by peripheral sensors	PC with A/D, digital I/O and serial input channels	numerous commercially available platforms	desirable to update patient's electronic medical record with logged data	Note 1	Note 1	Note 1	Note 1	Med	3	3	now	1	5
Medical image analysis	facilitate diagnoses and interventions	local processing and visualization of medical images; pre- and post-trauma holomer comparison	various commercial, research and open-source medical image analysis software packages		Note 1	Note 1	Note 1	Note 1	High	4	5	5-7 yrs	4	5

Notes

1. Assumes the capability is realized as software running on the on-board computer
2. Wireless versions available in 1-3 years
3. Worn by soldier, so no incremental consumption of NG-LSTAT resources
4. Higher if medical images are in data stream, lower if not

Table 2-6 Telecommunications

capability	purpose(s)	technologies	source / example	comments	Consumption					Benefits		Availability		Inter-dependency 1=low, 5=high
					cube (m3)	power (W)	weight (kg)	comm bandwidth (Mbps)	CPU usage	added value 1=little, 5=great	possible synergy	time frame	R&D required 1=none 5=much	
LSTAT-area networking	support communication among high data rate devices in/on LSTAT and in/on patient	wireless ethernet hub	many commercial and Mil-spec versions available	most useful if built-in	0.01	10	0.5	10-100	Low	3	4 (Note 1)	now	1	5
	support communication among low data rate devices in/on LSTAT and in/on patient	Bluetooth transceivers	very short range	most useful if built-in; multiple transceivers required	neglig	1	0.1	1	Low	5	4 (Note 1)	now	1	5
Wide area networking	provide global coordinates	GPS receiver	many commercial and Mil-spec versions available	could be interfaced or built-in	0.05	5	1	0.1 (Note 3)	Med	3	4 (Note 2)	now	1	2
	provide global communication	satellite phone	many commercial and Mil-spec versions available	could be interfaced or built-in	0.05	50	2	0.1	Med	5	5 (Note 4)	now	1	3

Notes

1. Multiple uses
2. Valuable for providing coordinates for evacuation
3. Depends on position update rate
4. Creates opportunities for telemedicine

2.2 Candidate Technologies for Integration to NG-LSTAT

2.2.1 Diagnostics – Medical Imaging

Table 2-1 lists imaging modalities such as digital X-Ray, which can be integrated into the NGLSTAT.

2.2.1.1: Digital X-Ray

Digital (or filmless) x-ray units are most commonly used for fluoroscopy, i.e., real-time x-ray imaging. An example of a portable x-ray unit is the OEC 9800 (GE Healthcare). It is a fully self-contained workstation on a cart that includes all of the above components. The image intensifier and digital plate are mounted at opposite ends of a "C-arm" that can be manually positioned relative to the patient; the C-arm is rotated about the patient's body (superior/inferior) axis and the entire unit is moved along the body axis. By encoding the C-arm motion about the body axis, limited tomographic imaging is possible. As currently configured, the entire station weighs 400 lbs, though weight savings are possible by substituting flat panel displays for the CRT monitors.

A portable digital X-ray imaging system consists of the following components:

1) Digital detector panel (digital plate) – essentially a large semiconductor x-ray receiver that is used in place of film. Typical dimensions are 40 cm x 40 cm x 1.5 cm thick.
2) X-Ray generator – an apparatus that generates high energy photons and collimates them through an intensifier that is pointed at a detector panel
3) System electronics – components that provide power and control functions
4) User interface – software, typically running on a ruggedized computer, that allows capture, viewing, storage and transmission of digital radiographs

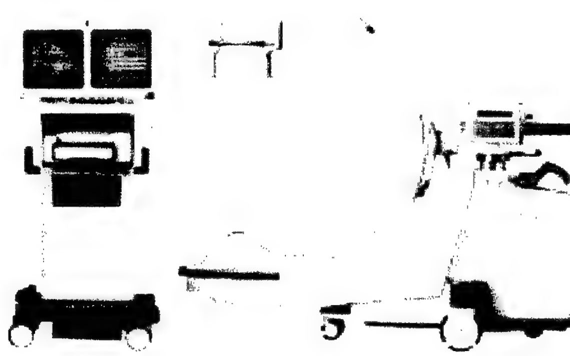

Figure 7 OEC 9800 digital x-ray system (GE Healthcare)

Digital X-ray is currently the highest resolution medical imaging modality feasible for use in combat casualty care. It can be used for a variety of diagnostic purposes, including delineation of skeletal injuries; detection of internal bleeding, locating embedded shrapnel, as well as for image guided interventions. In major trauma, x-ray is of particular value in identifying spinal injuries that would call for special precautionary immobilization of the patient prior to evacuation. Field ruggedized digital x-ray equipment is available for combat casualty care as shown below.

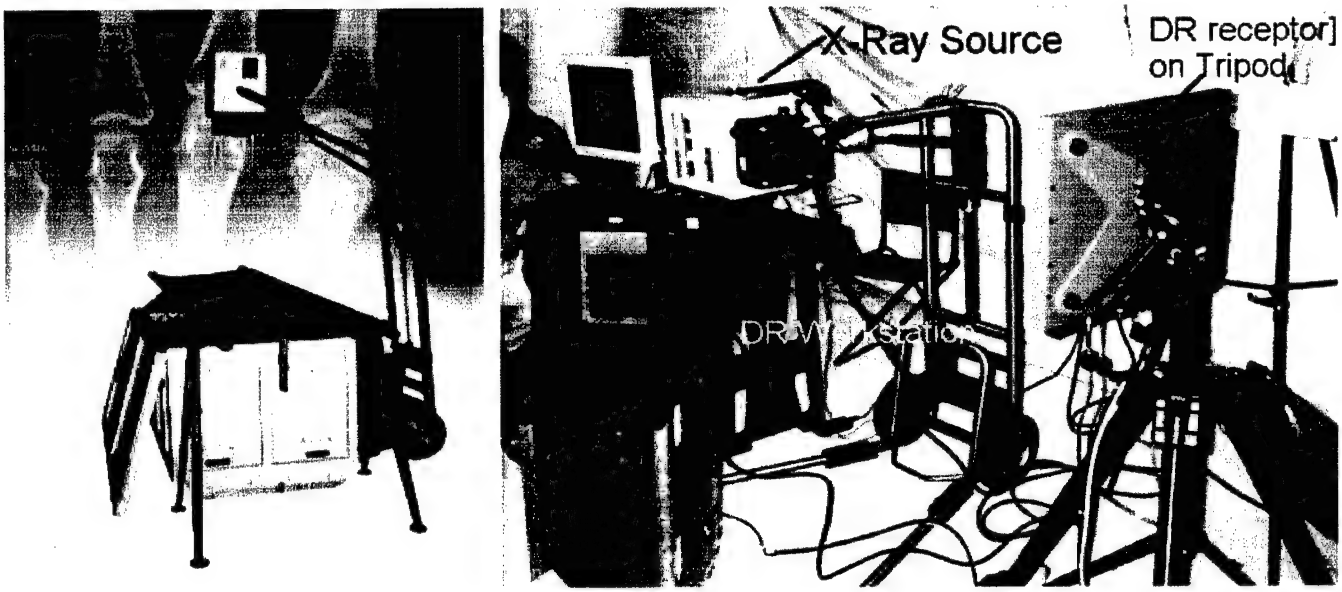

Figure 8 portable digital x-ray equipment (Varian, Inc.)

Because of power, cube and weight specifications of contemporary x-ray generators, it is not feasible to integrate an entire digital x-ray system into NG-LSTAT for stand-alone use in the field. It is reasonable, however, to expect them in mobile medical vehicles such as AMEV. The most likely configuration is for the intensifier to be on an articulated boom above the patient and the digital plate below the patient. It is also desirable for there to be, at minimum, translation of the intensifier/receiver pair along the patient's body axis. This suggests that the digital plate be mounted <u>in</u> the LSTAT on rails that allow it to slide along the length of NG-LSTAT below the patient couch. Doing so requires that the plate be lightweight and ruggedized against shock, vibration and extremes of temperature and humidity to a higher standard than hospital use. This configuration can be enhanced by addition of a single degree-of-freedom robotic positioning device that moves the digital plate in synchrony with the overhead intensifier. It is not necessary to build the digital plate into NG-LSTAT, but it must be easy to load one into NG-LSTAT. This could be accomplished with another simple mechanism akin to a tray-loading CD drive in a computer.

An alternative to the robotic positioning mechanism is to place multiple digital plates at fixed locations below the patient. It may also be desirable to articulate the plate(s) at various angles to the nominal anterior-posterior imaging direction. This increased flexibility will come at the cost of larger cube requirements to accommodate all possible articulation angles. Regardless of the physical configuration, it will be useful to view and store acquired x-ray images on NG-LSTAT, e.g., on the Secondary Data System computer, to ensure that acquired images stay with the patient as he is transported.

2.2.1.2: Portable Ultrasound

A variety of commercially portable ultrasound systems are available with capabilities that rival much larger clinical units. They range in size from a PDA to a laptop computer, not including the ultrasound probe itself.

The most advanced of these is MUSTPAC (Medical Ultrasound, Three-dimensional- Portable with Advanced Communication) developed by Pacific Northwest National Laboratory. MUSTPAC acquires 3D ultrasound images and is intended to allow diagnostically useful ultrasound scans to be taken by a field medic and transmitted to a remote specialist who interprets the images and provides verbal assistance (this mode is referred to as "teleultrasound"). MUSTPAC is bundled into a 22-pound backpack load, much of which is batteries. It has been used in Bosnia and on Mt. Everest for teleultrasound consults.

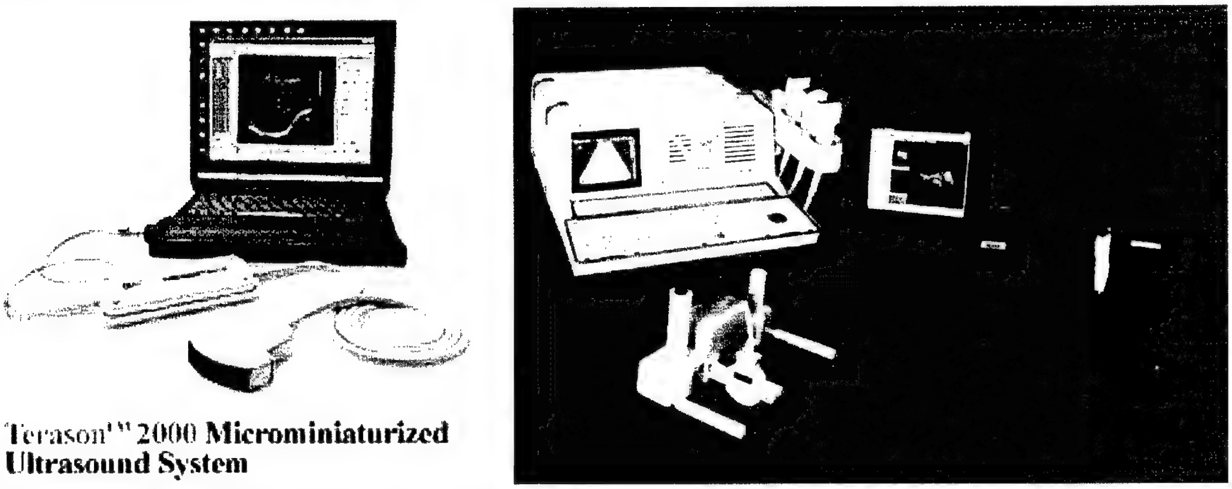

Figure 9 Portable ultrasound units. Left: Terason 2000 (Teratech Corporation); right: MUSTPAC

Ultrasound imaging could be integrated to NG-LSTAT in a number of ways, the simplest of which is to network its embedded computer to the Secondary Display System computer. An alternative is to build the portable ultrasound functionality into the SDS itself, which could be readily accomplished by adding ultrasound software and appropriate hardware interfaces.

2.2.1.3: Other Medical Imaging

The Radio Frequency Triage System (RAFTS), a new technology under development at the Uniformed Services University of Health Sciences, will be useful in identifying life-threatening internal bleeding, particularly hematoma and pneumothorax.

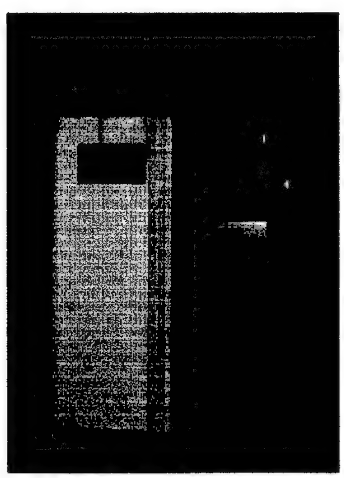

Figure 10 Radio Frequency Triage System (RAFTS)

2.2.1.4: Medical Image Display

Display of medical images acquired in the field on NG-LSTAT' is a straightforward yet potentially valuable use of its Secondary Display System. In addition to display on traditional CRT's and flat panels, a variety of novel techniques are available for presentation of medical images. These include wearable, or heads up, displays, most of which use small LCD panels, though direct "writing" by a laser onto the user's retina is also possible, as in the system being developed by Microvision, Inc. shown below.

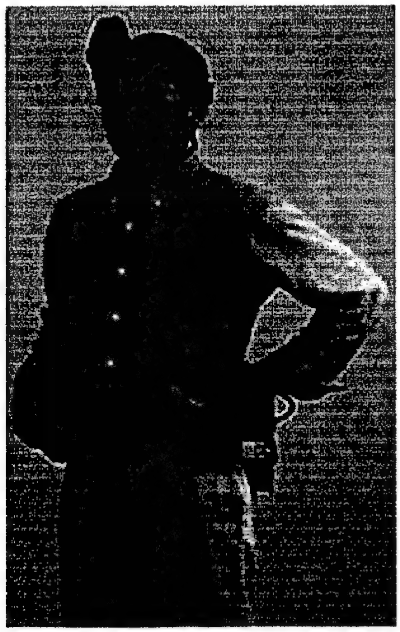

Figure 11 example of a wearable Heads Up Display

Heads up displays create the opportunity for use of artificial reality techniques that combine medical images with the medic's natural optical view path. Alternatively, images can be reflected on half silvered mirrors as in the Image Overlay system (CASurgica, Inc.) and the Sonic Flashlight (University of Pittsburgh and Carnegie Mellon University) as shown below.

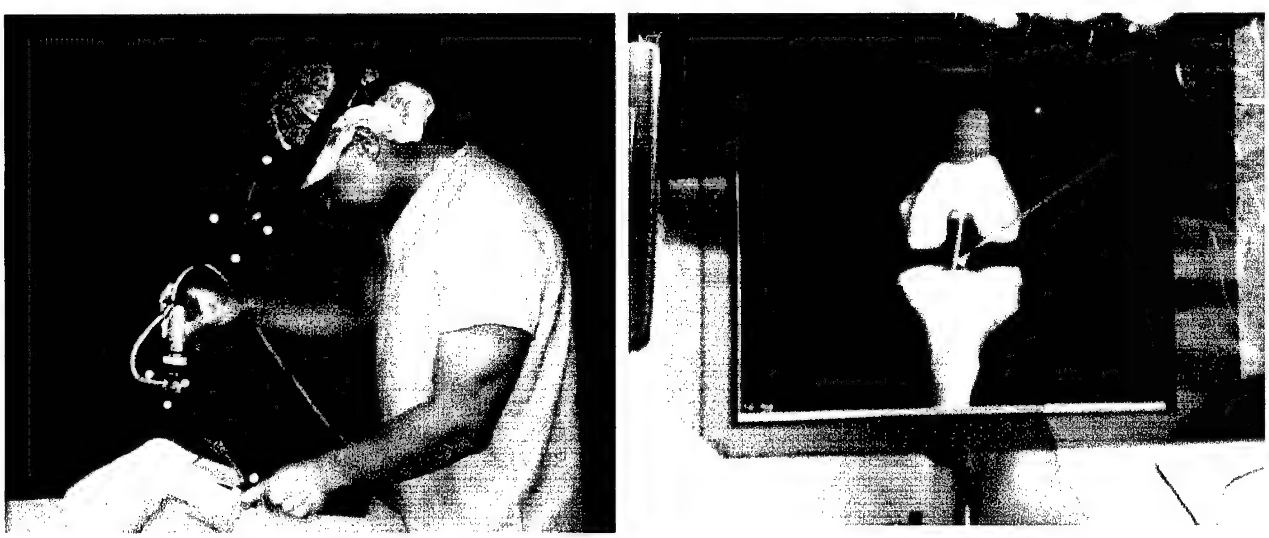

Figure 12 Image Overlay. Left: viewer and optically tracked medical instruments; Right: artificial reality display

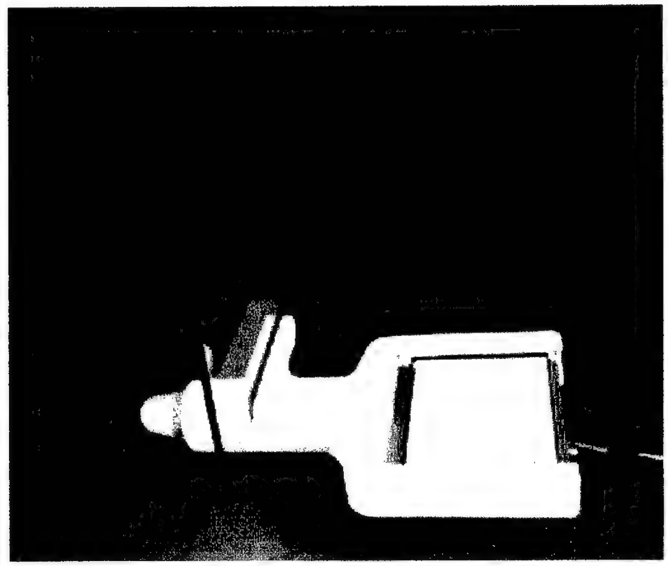

Figure 13 "Sonic Flashlight" device. Left: ultrasound image as it appears to viewer; Right: prototype device showing ultrasound probe, display unit and mirror

We anticipate that future warfighters will carry a digital dog tag that stores a variety of information, including pre-deployment medical images that capture the soldier's baseline anatomy. In the extreme, this will be a full 3D holomer generated from one or more sources (MR, CT, X-rays and ultrasound). NG-LSTAT should therefore have the capability to download medical images and other data from digital dog tags; this is discussed further in section *2.2.6 Informatics / Medical Decision Support.* Given the availability of pre-injury medical images and in-field imagers such as digital x-ray or ultrasound, the next logical step is software that allows visualization of both data sets simultaneously, e.g., using artificial reality techniques.

2.2.2 Other Diagnostics

Advances in sensing a variety of physiological parameters are being contemplated for military use. In some scenarios, each warfighter's health status will monitored and that information fed to upper echelons. We classify physiological sensors as three types: external/wearable, implanted and catheter-based. Examples and requirements of all three types of sensors are presented in Table 2-2.

A good example of wearable sensors developed for the battlefield is the Warfighter Physiological Status Monitor (WPSM) depicted in Figure 14. WPSM is a suite of wearable sensor modules that communicate wirelessly to a central hub worn on the belt. The hub collects and analyzes data from the following sensors: LSD (Life Sign Detection: ECG, Respiration, Body Posture), BISD (Ballistic Impact Detection) determines whether a soldier has been hit by a projectile, thermal state (estimates and provides warning of approaching

hyperthermia) Sleep monitor (Sleep Watch) and "Drink-O-Meter", which tracks water consumption.

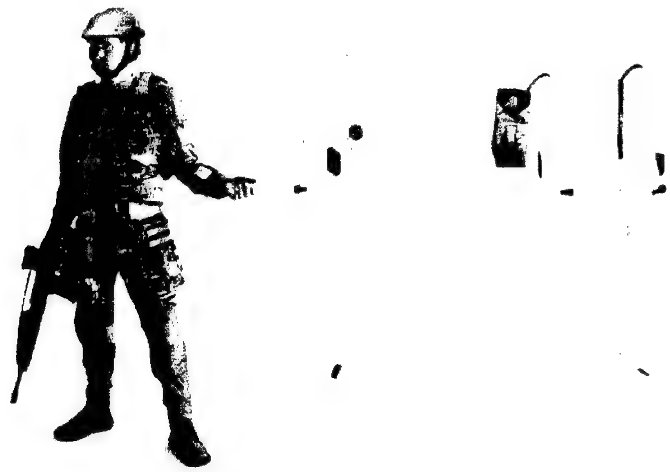

Figure 14 Warfighter Physiological Monitoring System (WPSM)

One result of DARPA's Advanced Biomedical Technologies program is the "Smart Shirt" (now commercially available from Sensatex, Inc.) that is a garment containing a network of sensors for heart rate, respiration rate, body temperature and caloric consumption. The Smart Shirt has an integrated data bus that can accept additional sensors. (Other smart garments have been prototyped to detect passage of a projectile by one of several means including breakage of optical fibers and acoustic signature detection). There are several companies developing other sensors for warfighter use, including non-invasive measurement of lactate and blood gases.

Though not yet as mature as wearable sensors, a variety of chronically implantable physiological sensors are under development in university laboratories and several companies. Based on Microelectromechanical systems (MEMS) technology, these devices incorporate transduction elements and signal processing electronics on one silicon substrate. Foreseen applications include measurement of blood pressure, blood oxygenation, and concentrations of glucose and lactate. A novel device being developed in the MEMS Laboratory incorporates wireless RF telemetry in the electronics package of a strain gauge sensor for assess bone strength. As an alternative to batteries, their approach also uses externally supplied RF energy to power the implanted chip. The main difficulties with chronic implantation are biological compatibility, especially fouling by the body's natural defense mechanisms.

We expect that some physiological sensors will eventually be standard issue for all warfighters, hence NG-LSTAT should be capable of receiving the data they produce. However, it is important that NG-LSTAT retain it's own physiological sensors even if they duplicate the capabilities of sensors worn by soldiers – if for no other reason than the potential for the soldier's sensors to be damaged or destroyed. Most wearable sensors use Bluetooth technology for data communications, hence NG-LSTAT should incorporate a Bluetooth port and an RF power source should chronically implantable sensors adopt the wireless power delivery scheme. NG-LSTAT's onboard computer should have software to automatically detect the presence of sensors worn by or implanted in the patient and it should log their data as well.

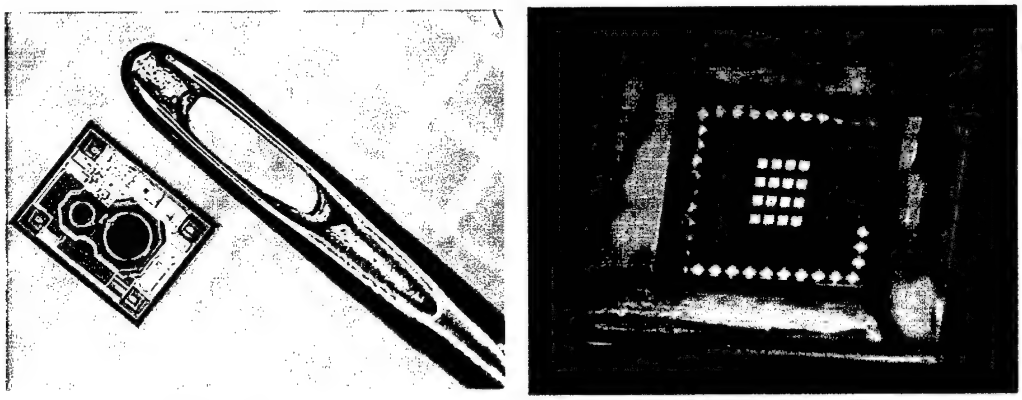

Figure 15 Left: MEMS pressure sensor manufactured (Kavilco, Inc., Moorpark, CA)
Right: membrane oscillator for measurement of biomolecules (Carnegie Mellon University)

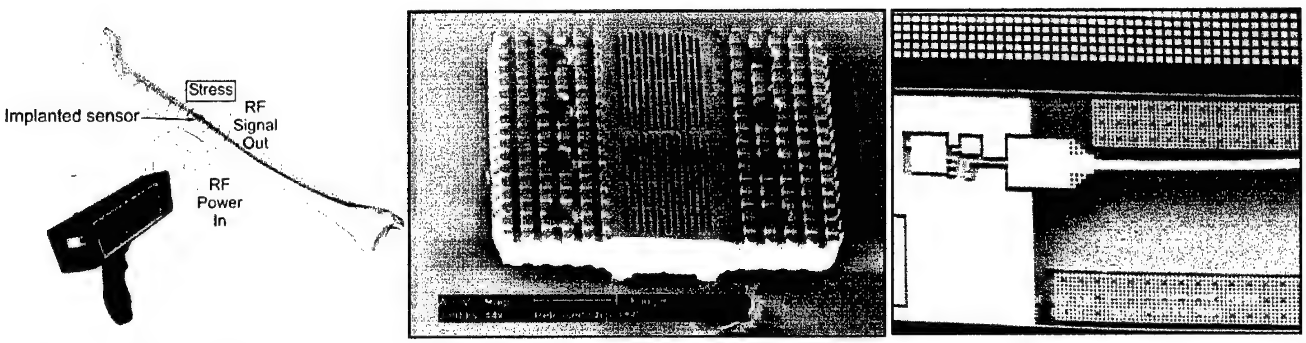

Figure 16 wireless measurement of bone strength. Left: system diagram; Center: MEMS-based sensor; Right: close-up of on-chip antenna

Another way to make *in vivo* measurements of fluid pressure, flow, temperature and other parameters is to embed technology similar to the implantable devices on the surface and at the tips of catheters (see for example Figure 17). These devices are commercially available and used primarily in cardiology and urology. An extension of this concept is the miniature robot that moves freely within the body. For example, robotic endoscopic micro-capsules have been developed for diagnosis and treatment inside the digestive system as an alternative to colonoscopy. Since this class of sensors may become a valuable capability for field use, NG-LSTAT should be equipped with interfaces to the associated electronics boxes.

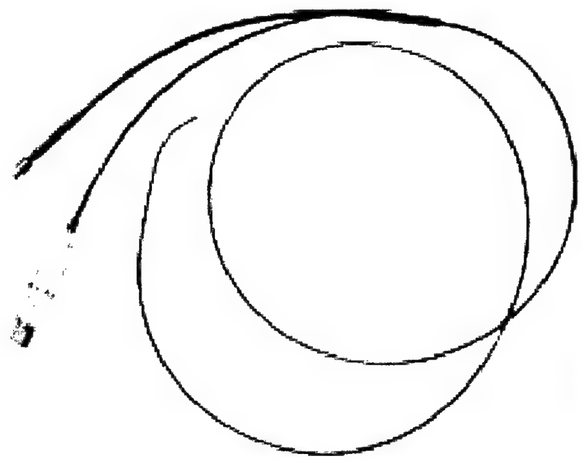

Figure 17 Left: catheter for in vivo blood pressure measurement Millar, Inc,); Right: sensors embedded in cather tip

2.2.3 Diagnostics – Other Sensors

Table 2-2 summarizes other devices that can be added to the NG-LSTAT. One very immediate opportunity is to outfit NG-LSTAT with a remote controlled camera that can be used for telediagnosis: visual examination of the patient from a safe location. By mounting the camera on a multi-link positioning mechanism, i.e., a robot arm, the entire body surface of the patient could be observed. A serpentine mechanism, such as the one shown in Figure 18, is preferred to the conventional manipulator because it provides equivalent visual coverage with far less swept volume and it can be used underneath the patient's blanket.

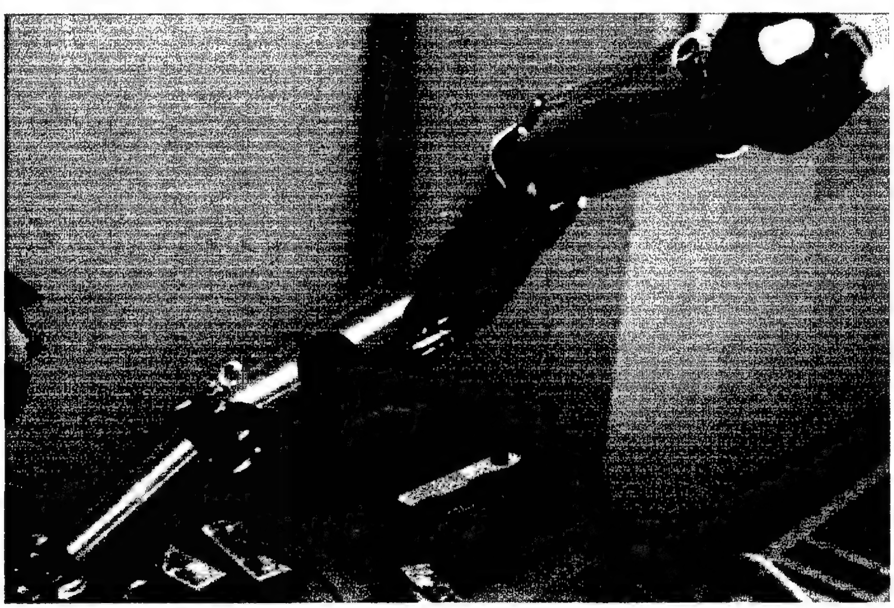

Figure 18 Serpentine manipulator (Carnegie Mellon University Biorobotics Lab)

2.2.4 Therapeutics – First Aid

Table 2-3 lists the technologies that can be used by the first responder during the initial treatment at the battlefield and can be integrated into NG-LSTAT.

2.2.4.1 Hemostatics

The fibrin bandage is a new technology in which human blood-clotting factors are impregnated in the cloth of the bandage; when applied to a wound, it actually becomes part of the blood clot. Special Operations medics have now been trained to use them. Though it is a passive device, hence requires no power or data communications, simply storing a supply of fibrin bandages in NG-LSTAT would ensure their availability.

High Intensity Focused Ultrasound (HIFU) is an active hemostatic device intended for the rigorous duties of the Battalion Aid Medic being developed by the University of Washington and the University of Mississippi. Designed to function as a self-contained unit, HIFU is used to detect bleeding and cauterize internal or external tissue without the need for antibiotics, surgery and in some cases anesthesia (Frank, et al, 2003). HIFU has a distinct advantage over existing cauterization techniques, such as electrocautery and lasers, because it can deliver energy deep within the body without damage to intervening tissue, and potentially from outside the body. Though not yet cleared by the FDA, preliminary results have shown that HIFU can occlude blood vessels, stop bleeding from hepatic and splenic injuries, and arrest hemorrhage from injured capillary beds and major blood vessels (Vaezy, et al, 2001). Because of its versatility and therapeutic value, it may be desirable to accommodate a HIFU unit in NG-LSTAT.

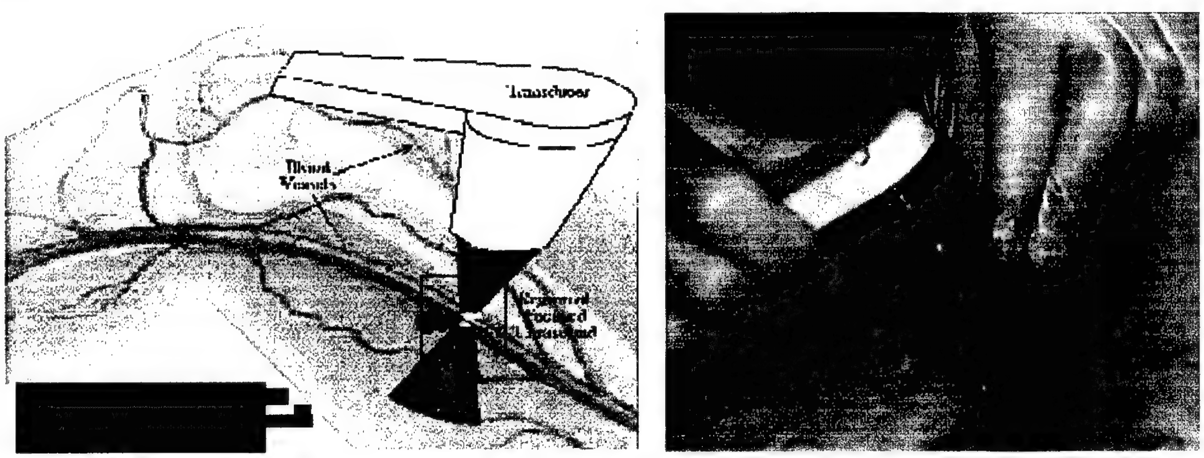

Figure 19 High Intensity Focused Ultrasound (HIFU). Left: system diagram; Right: clinical trial in animal model

2.2.4.2 Clearig Airways

A common problem that first responders have while inserting endotracheal (ET) breathing tubes is lack of knowledge of where the tip of the tub actually is. For this procedure, commercially available surgical navigation and image guidance technologies could both beneficial. By affixing an optical or electromagnetic sensor to the tube, a surgical navigation system can give the medic a rough indication of the tube's position in real time in a computer graphic. That visualization can be improved upon by adding anatomical data from an atlas, the

patient's own 3D anatomical record (see section 2.2.1.4: Medical Image Display) or with live ultrasound. Since intubation does not require millimetric position, electromagnetic tracking systems like MiniBird (Ascension Technology Corporation) will likely suffice, even though their measurements are prone to disturbance by metal artifacts near the sensor. To use such tracking for this application, NG-LSTAT would have to contain a base station mounted near the patient's neck area (e.g., below it) and a supply of ET tubes with embedded sensors.

A completely unprecedented approach, to our knowledge not under development anywhere, is for a medical robot to actually perform the intubation. One approach is for a manipulator to place a conventional ET tube; an alternative is for a serpentine manipulator with a hollow center to literally snake its way through whatever is blocking the airway.

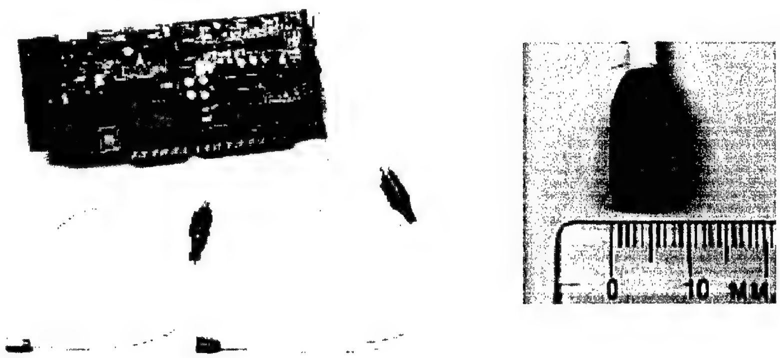

Figure 20 miniBird electromagnetic position tracking system

2.2.4.3 Catheterization

Once airway, breathing, bleeding and circulation have been attended to, a medic's next task is often to start an intravenous (IV) line by introducing a needle into a vein. In most cases, the IV line is peripheral, though there are instances when a catheter is passed through the vein all the way to the vena cava or right atrium of the heart i.e., a "central catheter," which might be advantageous for infusing fluids. A future concept is to prolong the "golden hour" with hypothermia induced by perfusing the body with chilled fluid via a central catheter [Tisherman 90].

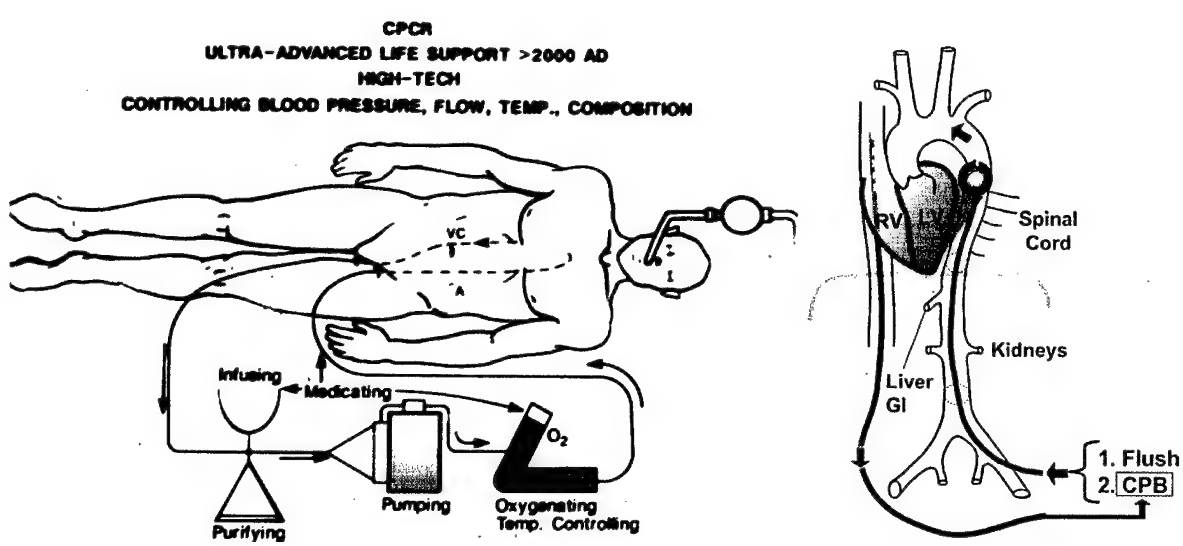

Figure 21 Hypothermia and "Smart Catheter" concept (Safar Center, University of Pittsburgh)

Even with training it can be difficult for the medic to start a catheter. Two advanced medical technologies can provide assistance. Portable ultrasound, described above in 2.2.1.2: Portable Ultrasound can be used to help the medic locate veins and visualize the needle as it is inserted. This might also be done with the help of a remote expert who provides live annotations to the medic's ultrasound display via a telementoring system, e.g., as illustrated in the following figure.

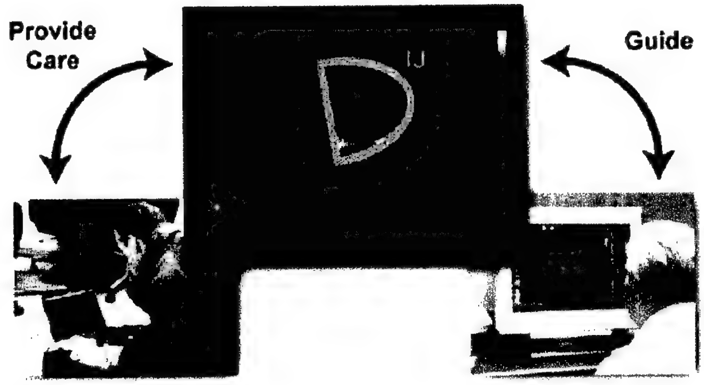

Figure 22 Notional telementoring scheme for assisting field medics with catheterization (Carnegie Mellon University and the University of Pittsburgh)

A second option is for a robot to provide assistance. Here the precedent is robotically assisted guidance of percutaneous instrument placement, a capability that is currently under development in several universities for catheter guidewire insertion, needle biopsy, and surgical oncology, examples of which are shown below.

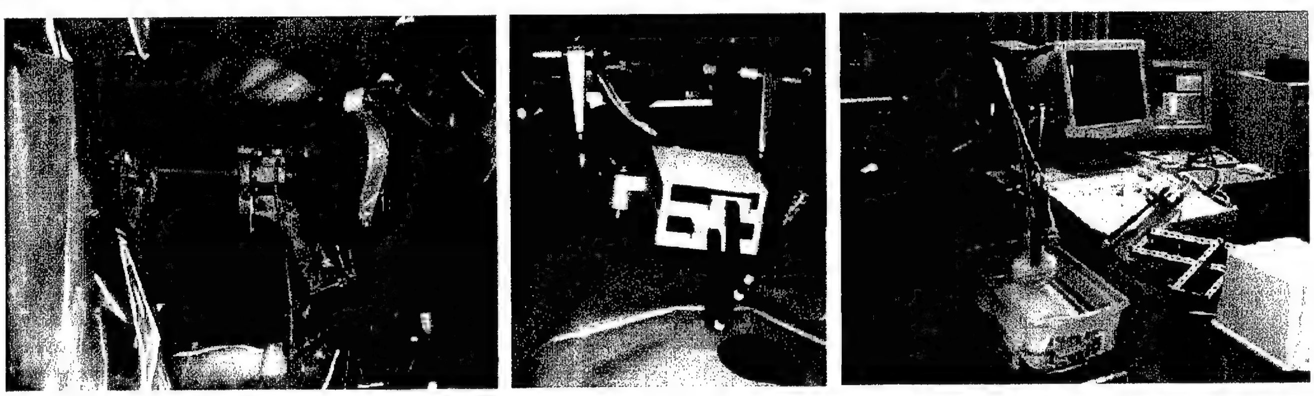

Figure 23 Examples of robots for guiding percutaneous instruments.
left: catheter guidewire insertion (University of Hull, UK);
center: biopsy needle placement (ARC Seibersdorf Research, Austria);
right: ultrasound-guided liver ablation (Johns Hopkins University)

For such a scheme to be viable, it is necessary to somehow relate the robot's coordinates to the patient's anatomy using image-based registration and/or a surgical navigation scheme. The Johns Hopkins system uses two robots, one to place an ultrasound probe and the other to place the needle guide. If NG-LSTAT is outfitted with a manipulator, e.g., as described above in *2.2.3 Diagnostics – Other Sensors*, that same arm could be used for either or both purposes.

2.2.5 Therapeutics – Secondary and Tertiary Care

2.2.5.1 Use of Medical Robots

With advances in medical technology, secondary and tertiary care is moving closer to the point of first response. Robotics is a key enabling technology of that trend because it 1) alleviates some medical expertise requirements on the part of caregivers and 2) allows care by experts from a distance. It is likely that robotics will play an increasing role in combat casualty care of the future and at some point, secondary and tertiary robotic interventions will occur while the patient is still on an NG-LSTAT. To explore the implications of that general scenario, we first provide a summary of the current state of art in medical robotics as well as its likely future. A more comprehensive discussion of the use of robots in medicine and surgery is the Final Report on the International Advanced Robotics Program's Workshop on Medical Robotics [11].

There are several classes of surgical robots, generally distinguished by their level of autonomy:

- Passive, in which the robot serves as a guide to the surgeon's hands but performs not interventional action of its own. Examples include the Remote Center-of-Motion (RCM) robots of Johns Hopkins and the Neuromate that locate guides through which a surgeon drives an instrument.
- Hands-on, in which the surgeon operates the device in the surgical field. An example is Micron, a hand-held instrument for vitroretinal surgery that senses and actively cancels hand tremor; another is ACROBOT, a special purpose manipulator for knee surgery.
- Teleoperated, in which the robot is in the surgical field but controlled by a surgeon some distance (usually a few feet, i.e., within the operating room) away. Examples include Zeus (Computer Motion, Inc.) and da Vinci (Intuitive Surgical Systems) that are used for a variety of abdominal and thoracic procedures, often as an alternative to laparoscopic surgery. The da Vinci is currently used for cardiac procedures (mitral valve repair and pacemaker epicardial lead placement), gastroenterological procedures (Nissen fundoplication, gastric bypass and esophageal surgery) and other procedures including radical prostatectomy and thymectomy.
- Active or autonomous, in which the robot acts on its own. Examples include RoboDoc, which is used to ream the channel to accept the femoral component in a total hip replacement, and Caspar, which is to machine bone surfaces to accept prosthetics in total knee replacement. Currently, autonomous surgical robots are actually pre-programmed, i.e., they do not sense and reason on their environment nor do they plan their own actions and reactions.

In all but the autonomous class, the surgeon is an integral part of the overall system, providing both the sensing (visual, and to a lesser extent, haptic) and the signal processing to close the control loop. Many surgical robots, including Neuromate and RoboDoc, are based on or strongly resemble industrial manipulators. A class of robotic tools is emerging that have features of both passive and hands-on robots.

Surgical robots are often used in conjunction with an image guidance system that is used to identify, localize, access, remove and/or interact with a region of interest within the patient using CT, MRI, x-ray or ultrasound. Image acquisition is followed by one or more stages of

image enhancement, particularly segmentation to define anatomical structures of interest. When used by a surgeon, the result is a computerized model, usually 3D, that he can use to visualize the patient's anatomy. Current state of art is for the surgeon to interact with this model to define surgical instrument trajectories that are then executed by the robot.

In order to meet accuracy, stiffness, safety, range of motion and dexterity requirements, contemporary surgical robots have multiple degrees of freedom, hence are generally bulky and costly. Surgical robots are currently too complex for medical teams to install and use without the assistance of dedicated technical teams in the operating room, which adds to their cost of use.

A major unsolved problem with autonomous surgical robots is the ability to sense and react to intraoperative soft tissue motion. As a consequence, today they are used predominantly in orthopaedics working to a fixed pre-operative plan to modify rigid bone and to a lesser extent in neurosurgery (the brain's geometry is very stable compared to other soft tissue). An important area of needed fundamental research is methods to accurately model and/or track deformation of soft tissue in real time.

A number of technological innovations in the next ten years will support increased use of surgical robots. Robots that can work within radiological environments (x-ray fluoroscopy, CT and MR) will be perfected, and when complemented with augmented reality techniques and intra-operative tracking of tissue deformation, will allow use of real-time 3D imaging for robot control. Improvements in component technologies such as computers, actuators, controllers and sensors will also contribute by reducing costs, increasing reliability and allowing miniaturization. Improvements in human-machine interfaces, especially haptics, and tighter integration with surgical navigation systems will make teleoperated robots much more useful. End effectors for non-reactive tissue destruction will emerge, reducing the risks associated with tissue dissection by a robot.

Figure 24 Left: daVinci laparoscopic surgery robot; Right: Penelope robotic scrub nurse

Tissue engineering is other therapeutic technology under development that might impact future use of robotics and combat casualty care. A number of groups, including teams at Carnegie Mellon, Stanford and the University of Michigan, and Sciperio, Inc., are using robots for

patterned deposition of biological materials in 3D. Though full-fledged tissue engineering is many years from being a viable therapy, robotic printing of growth factors and other materials could become a useful technique sooner.

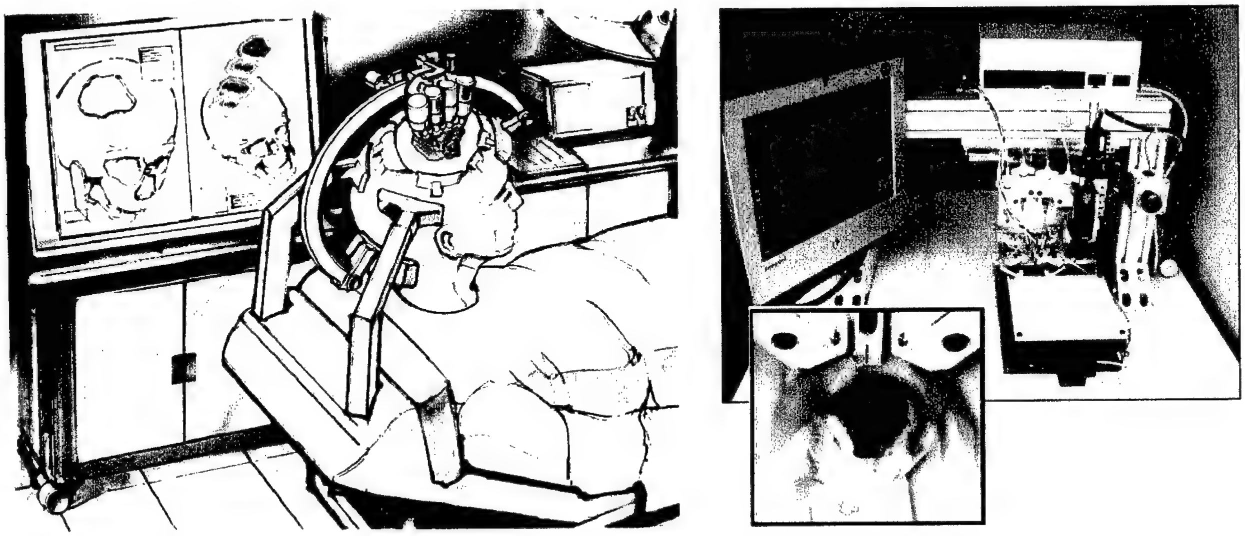

Figure 25 Robotically assisted tissue engineering (Carnegie Mellon University)
Left: artist concept; Right: robotic 3D printer; Inset: early trial on rodent model

2.2.5.2 Role of NG-LSTAT

A noted above, it will become increasingly possible to project secondary and tertiary interventions toward the battlefield. However, for reasons of cost and complexity it seems unlikely – at least within the next decade – that the technological capabilities will be part of NG-LSTAT. However, it is reasonable to expect that more involved therapies will be possible in field vehicles, e.g., AMEV, hence NG-LSTAT itself will be part of a larger interventional system. Assets that might be integrated into NG-LSTAT such as light-duty manipulators, position tracking systems and diagnostic sensors would be used to support robotic and telerobotic interventions.

2.2.6 Informatics / Medical Decision Support

Table 2-5 lists the informatics and medical decision support systems that can be integrated into NG-LSTAT.

On-board Computer / Secondary Display Workstation

In order to improve the existing LSTAT, the data collected from various sources needs to be transformed into useful information. At minimum, NG-LSTAT onboard computers should summarize patient data to facilitate its interpretation by the medic. This can be implemented today. In the future, additional systems should provide intelligent clinical decision support, data interpretation, patient assessment, and ultimately computer assisted diagnosis and recommendation of therapies.

A clinical decision support system (CDSS) is a computer program designed to help health care providers apply codified medical knowledge to a specific patient given that patient's symptoms and measured physiological parameters. Main components of a CDSS are:

1) Medical Knowledge. The representation of medical knowledge varies from system to system. For instance, knowledge about a drug could be represented in form of a pharmacokinetic model that describes the behavior of that drug.

2) Patient Data. The medical knowledge contained in the CDSS is used to interpret patient data. For instance, patient characteristics are used to set the parameters for a drug behavior.

3) Case-specific advice. The result of applying medical knowledge to patient data. For instance, applying drug behavior to patient data may result in a suggestion about the dosage of the drug for that particular patient.

An increasing number of clinicians are using computerized speech recognition systems to streamline the reporting process with automatic medical dictation. Commercially available solutions for are improving, hence we can expect that they will be viable for use in the field in the near future. With a speech recognition system integrated into DDLS, the first responder's voice can be used for medical data entry and other interaction with NG-LSTAT.

The Personal Information Carrier (PIC) can store not only information on identity and blood type, but also allergies, past medical history and medical data needed to perform immediate triage of combat casualties. It could also be used to store a pre-deployment holomer of the soldier. In the future, PIC's will communicate with other devices using wireless technology resulting in the Wireless Electronic Information Carrier. We assume data stored on the WEIC will be transmitted to the NG-LSTAT on-board computer as soon as the patient is placed on-board and that data collected by NG-LSTAT will be also stored on the WEIC. This requires, at minimum, a wireless link between the two. Further advancements could be developed to make these processes automatic and transparent to medical personnel.

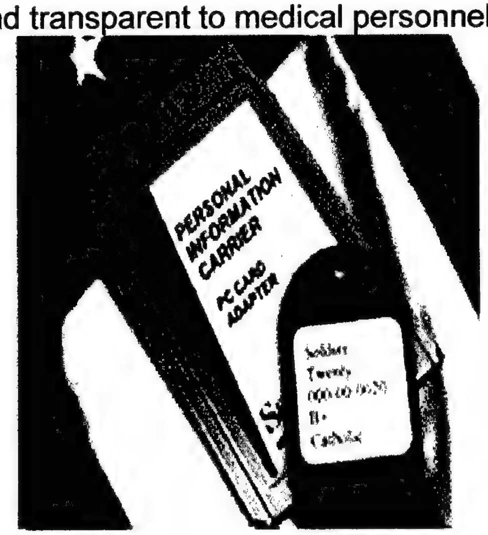

Figure 26 Personal Information Carrier

2.2.7 Information Systems and Telecommunications

Table 2-6 lists possible telecommunications means which can be implemented on NG-LSTAT. The quality of communication between health care providers strongly influences the quality of care. Communication in the battlefield scenario is essential for wounded patients who are under the shared care of several health care providers (medics, Physician assistants and physicians). Insufficient communication between these care providers may cause wrong diagnosis or therapy.

3. Evaluation of Candidate Technologies

3.1 Top Five Technologies

After analyzing the systems hypothesized in the tables, the top five technologies were selected. These systems were selected for their high potential benefits as well as clear opportunity for integration in the near-term, i.e., within 3 years or less. Further, they provide a foundation for additional, future enhancements.

1 On-board informatics & medical decision support
2 Wireless data communications
3 On-board robot manipulator for telediagnosis and future interventional support
4 Digital x-ray plate positioner
5 Portable ultrasound

Their integration with NG-LSTAT is described in greater detail below.

3.2 Discussion

3.2.1 On-board Informatics & Medical Decision Support

Medical decision support systems such as Special Operations Forces Medical Handbook (SOFMH) and Special Operations Medical Decision Support (SOMDS) have proven to be a valuable asset to the field medic. This capability can be improved upon through use of patient data collected by physiological sensors, a function already performed by the current LSTAT. Software running on NG-LSTAT's on-board computer should therefore combine these capabilities in a more automated system. In addition, the current LSTAT does not allow for complete transmission of medical data to the higher echelons of care, which can also be remedied with new software and upgrades to the telecommunications subsystem. Specific modifications to the current DDLS (Display and Data Logging Subsystem) and Secondary Data Display are:

1. Consolidate all functions into a single workstation.
2. Provide interfaces that support all data communications protocols, including Bluetooth, 802.11x, 802.15, Ethernet, USB and RS-232
3. Support telediagnosis and teleconsultation
4. Provide dedicated interfaces to the WEIC and WPSM hub
5. Host the application software for both portable ultrasound and digital x-ray image acquisition, viewing, storage and transmission
6. Host the software for control of robotic positioning devices and instrument position tracking systems

These capabilities are those of a high-end contemporary laptop computer.

3.2.2 Wireless data communications

The capability to interface with various sensors and transmit data to higher echelons of care – not possible currently – transforms NG-LSTAT into a telemedicine system. Upgrading its data communications is also necessary to enable future interfaces to packages worn by the soldier such as WPSM and WEIC.

3.2.3 On-board Robotic Manipulators

A light-duty manipulator that can position a camera will enable observation and detailed inspection of a patient by a remote physician. The robotic requirements for this application are full coverage of the patient and minimum swept volume, suggesting the use of serpentine mechanisms; the key telemedicine requirement is low-latency bi-directional telemetry with, at minimum, slow-scan video bandwidth on the uplink. Adding a serpentine manipulator will actually have only minor impact on LSTAT's hardware infrastructure. With minor modifications to its control system and an end-effector that allows it to pick up other tools, the same robot arm can also provide additional functionality such as

- serving as a third hand for the medic, e.g., to hold an ultrasound probe in place;
- moving an ultrasound probe under the control of a remote physician;
- positioning needle guides; and
- spraying antiseptics and antibiotics onto wounds.

A concept for incorporating serpentine manipulators into LSTAT is shown in the sketch below, in which three arms are being used for 1) video observation and inspection, 2) ultrasound examination, and 3) positioning a needle driver.

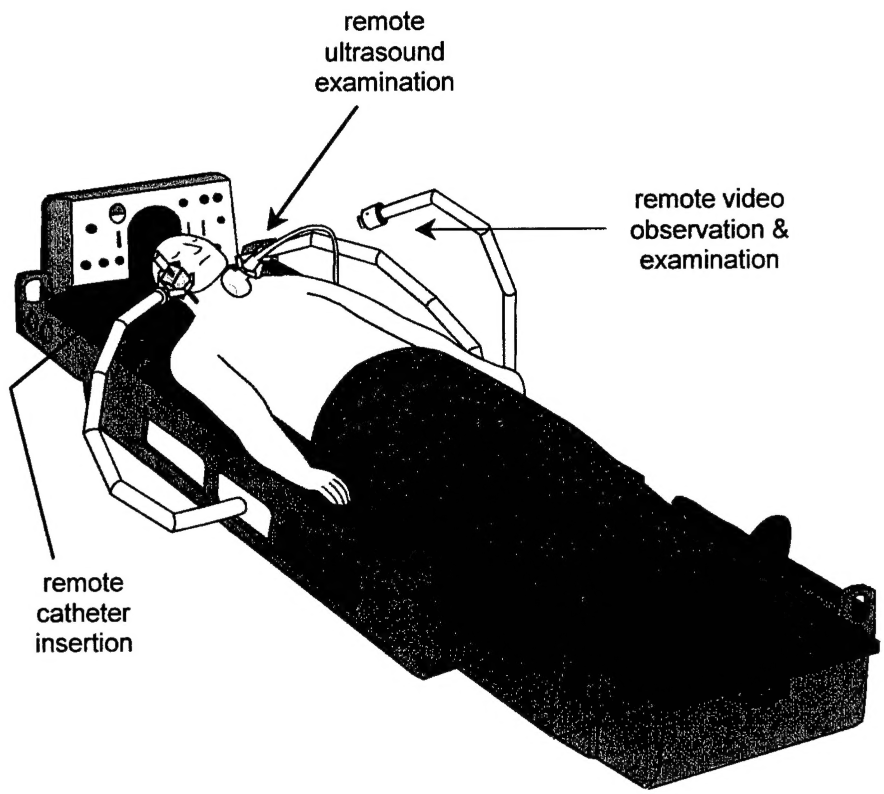

Figure 27 Adding serpentine manipulators to NG-LSTAT creates several opportunities for remote diagnosis and interventions

3.2.4 Digital X-ray

A digital x-ray system will enable high-resolution medical images of the patient to be taken without removing him from LSTAT. Presumably, the most far-forward an x-ray source will be is inside an AMEV (or equivalent) that is designed to accept one or more NG-LSTAT's

Accommodating the plate in the space below the patient litter requires a re-design of LSTAT. Ideally, the plate should be movable to any location along the patient's superior/inferior axis, suggesting that the plate be rail-mounted and moved by an electromechanism that servos to the position of the x-ray collimator. The NG-LSTAT docking procedure, therefore, will need to include linking the controllers of the collimator positioner and the plate positioner, which could occur automatically. It may be possible to save NG-LSTAT weight by loading the plate into NG-LSTAT when it arrives at the AMEV. A concept for loading digital x-ray plates onto an positioning system consisting of two parallel rails upon a which rides a carriage that holds the digital plate itself.

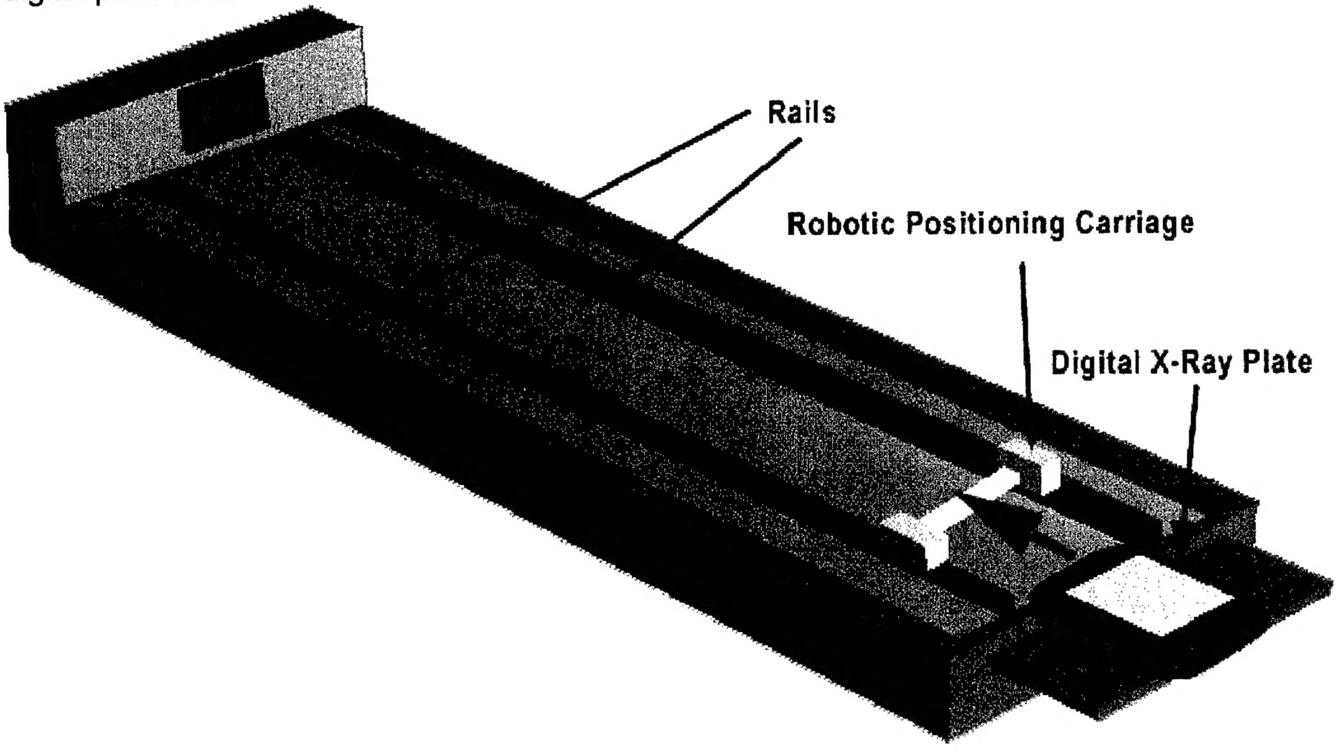

Figure 28 A digital x-ray plate can be readily inserted into NG-LSTAT and moved by a robotic positioning mechanism.

3.2.5 Portable ultrasound

Ultrasound units rivaling clinical systems can now be obtained in packages no larger than a laptop computer. That being the case, addition of ultrasound capability to NG-LSTAT amounts to a software upgrade and incorporation of an ultrasound probe, neither of which have a profound effect on LSTAT itself. The payoff, however, is the ability to acquire diagnostic images at the point of first response, which can be valuable both to the medic and in a telemedicine context. Because it has 3D imaging capability, the MUSTPAC-3 system is the system of choice. It would have to be modified to run on NG-LSTAT's on-board workstation, which would provide all image acquisition, storage, and visualization capabilities. Transmission of ultrasound data to remote physicians will require the higher bandwidth of NG-LSTAT's upgraded telecommunication system.

3.3 Recommendations

There are clear opportunities to make better use of LSTAT's by making minor enhancements that enable telediagnosis and medical decision support. Further research, development and engineering is warranted to realize those capabilities in NG-LSTAT.

We have grouped the suggested NG-LSTAT enhancements into three timeframes:

Near-term (3-5 years)

- Upgrade and consolidate computing and telecommunications capabilities.
- Incorporate hardware and software needed to support digital X-ray and ultrasound diagnostic imaging.
- Provide interfaces to the WPSM hub and the WEIC.
- Develop software to assimilate data collected from all physiological sensors and use it as part of an intelligent medical decision support system.
- Add one or two serpentine manipulators for telediagnosis and future diagnostic and intervention support.

Mid-term (5-10 years)

- Explore the use of on-board manipulators for remote ultrasound examinations.
- Explore the use of on-board manipulators for robotically assisted catheter and needle insertion
- Explore the use of on-board manipulators for remote wound treatment
- Add continuous speech recognition capability and natural language processing for verbal interaction with the NG-LSTAT on-board computers.

Long-term (>10 years)

- Explore the use of on-board manipulators for additional remote and possibly autonomous secondary interventions.

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